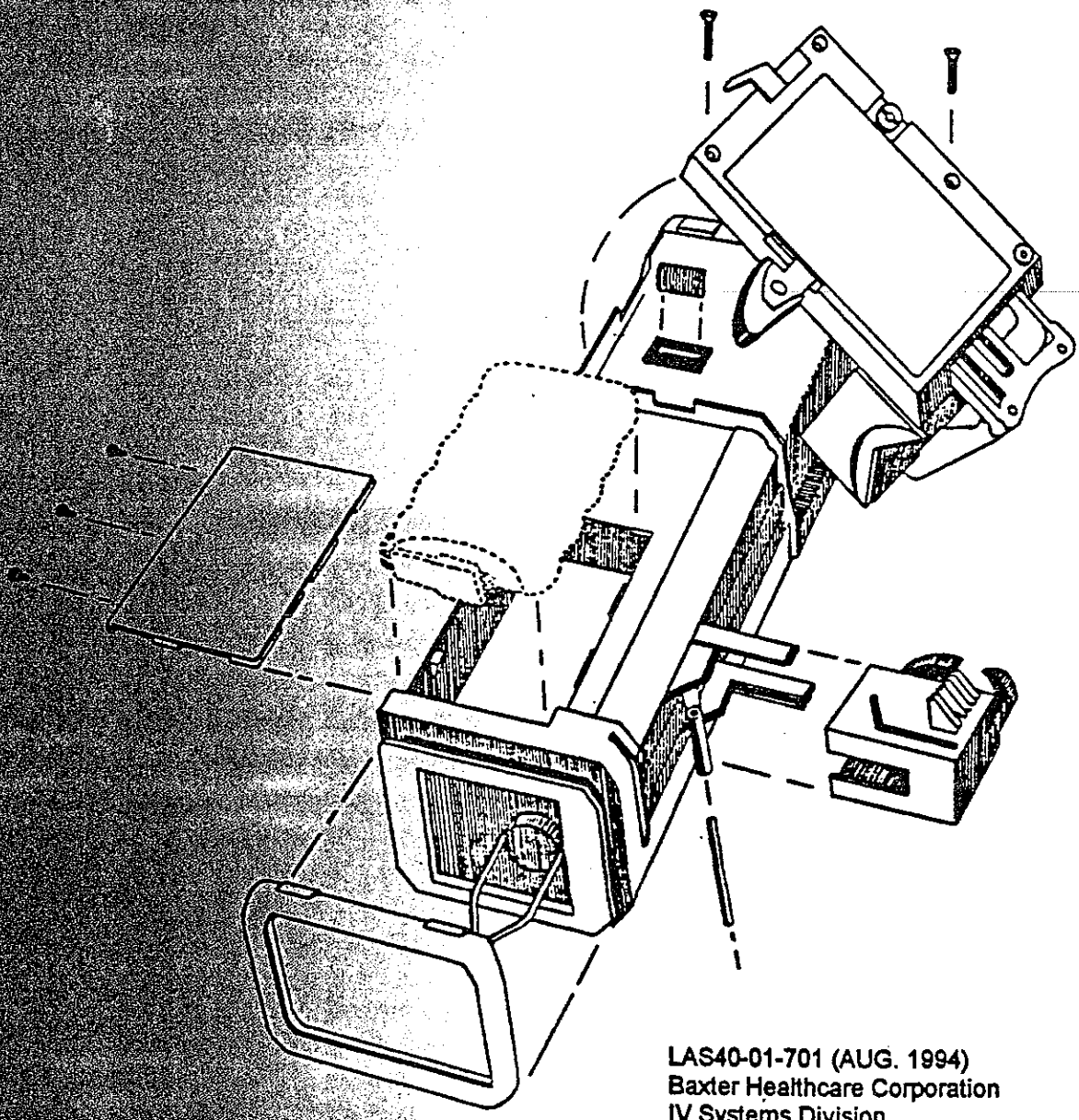
Model AS40A Infusion Pump Technical Manual



LAS40-01-701 (AUG. 1994)
Baxter Healthcare Corporation
IV Systems Division
Deerfield, IL 60015

I.V. Systems Division

er Healthcare Corporation
ute 120 & Wilson Road
Round Lake, Illinois 60073-0490

708.546.6311

Baxter

RE: AS40A Infusion Pump Technical Manual

Dear Biomedical Department:

Attached is a copy of the Auto Syringe® AS40A Infusion Pump Technical Manual. It represents earlier versions of software (A002P002 & A003P003) and may not be applicable to the software version you are currently using. We are currently revising the technical manual to include the newer software versions.

The enclosed Field Performance Check Procedure, 07-19-02-511, replaces the "AS40A Field Performance Check" on page 14 of this technical manual. This procedure can be used for a basic check out procedure and preventative maintenance programs that might be required by your institution.

Please note that this manual is an "informational technical manual" and is not intended for service repairs, assembly replacements, or calibration. Additional training and procedures are required before individuals can be authorized to repair, assemble, or calibrate the AS40A. Baxter claims no liability for individuals servicing the device without training.

For any further questions, please contact Product Service Management at 1 800-THE-PUMP (1-800-843-7867), (option #3).

Thank you,

Ken Ga Nung

Ken Ga Nung
Product Manager
Electronic Infusion Systems

General Information 1

About This Manual

This manual is intended for use by technical service personnel. The procedures described here are not suitable for general users. The calibration and configuration access codes are for use only by authorized technical service personnel.

The text uses the following general rules of notation:

" ... " (quotes) are used to differentiate names from units of measure.

> For example, "mL/hr" refers to the name of an operating mode, whereas mL/hr is a unit of measure.

[...] (square brackets) denote text prompts as they appear on the LCD panel.

> For example, [ML/HR] is the exact text that appears on the bottom line of the LCD when selecting the "mL/hr" mode.

< ... > (angle brackets) enclose data exactly as it is entered on the keypad.

> For example, <123><confirm> means: "type the numbers 1, 2, and 3, and then press the key labeled 'confirm'."

This manual covers pumps using Software Revision A002P002 or A003P003 only.

Product Description

The AS40A infusion pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate continuous or intermittent infusion via intravenous (IV), intra-arterial (IA), epidural, or sub-cutaneous routes of administration.

The AS40A accepts standard disposable syringes from 1 mL to 60 mL in size. A numeric keypad provides for simplified programming and overall ease of use. Safety and effectiveness are reinforced by pre-programmable bolus operation, titration of a dose without interruption of fluid flow, and easily understood alarm and warning messages.

The AS40A is field configurable. This allows technical support personnel to select the features that apply to the particular clinical setting. Configurable options include; syringe size and manufacturer, automatic syringe size recognition, infusion program modes, maximum infusion rate, selectable occlusion pressure sensitivity. and an auto-lock feature. The configuration can be easily reviewed by the user.

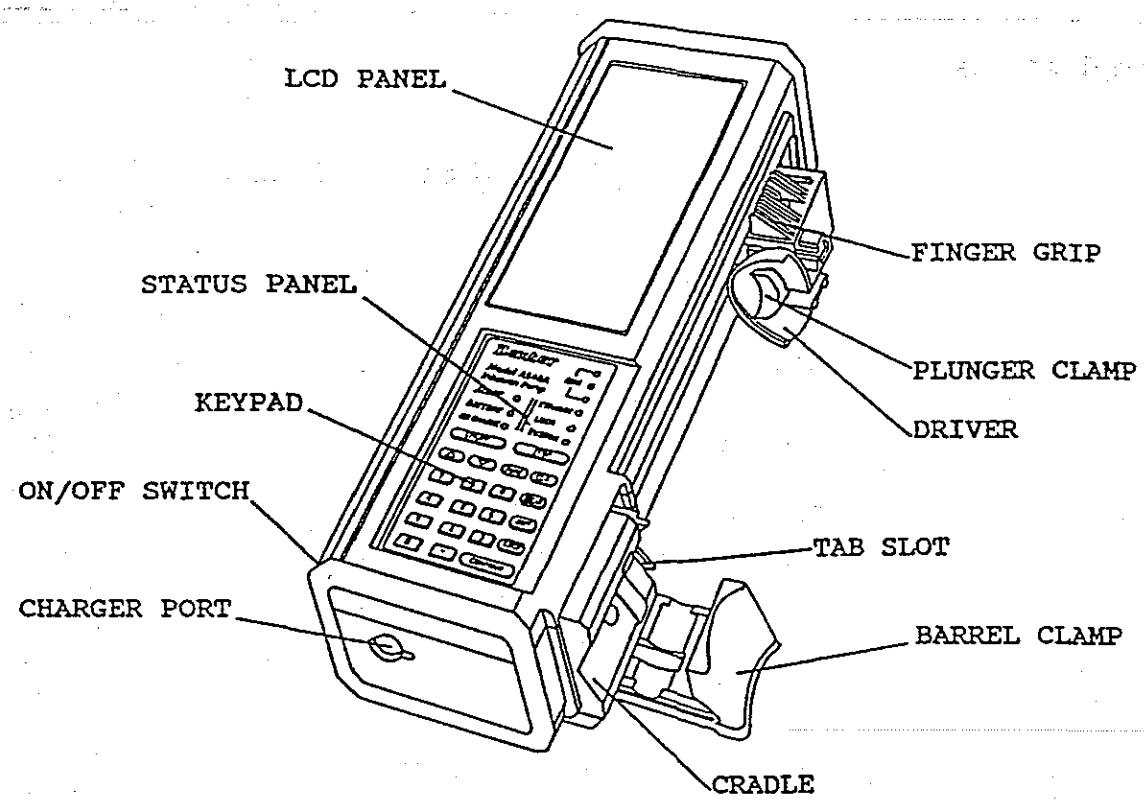
The AS40A can run on its internal rechargeable battery pack or can be operated while the battery charger is connected to AC power.

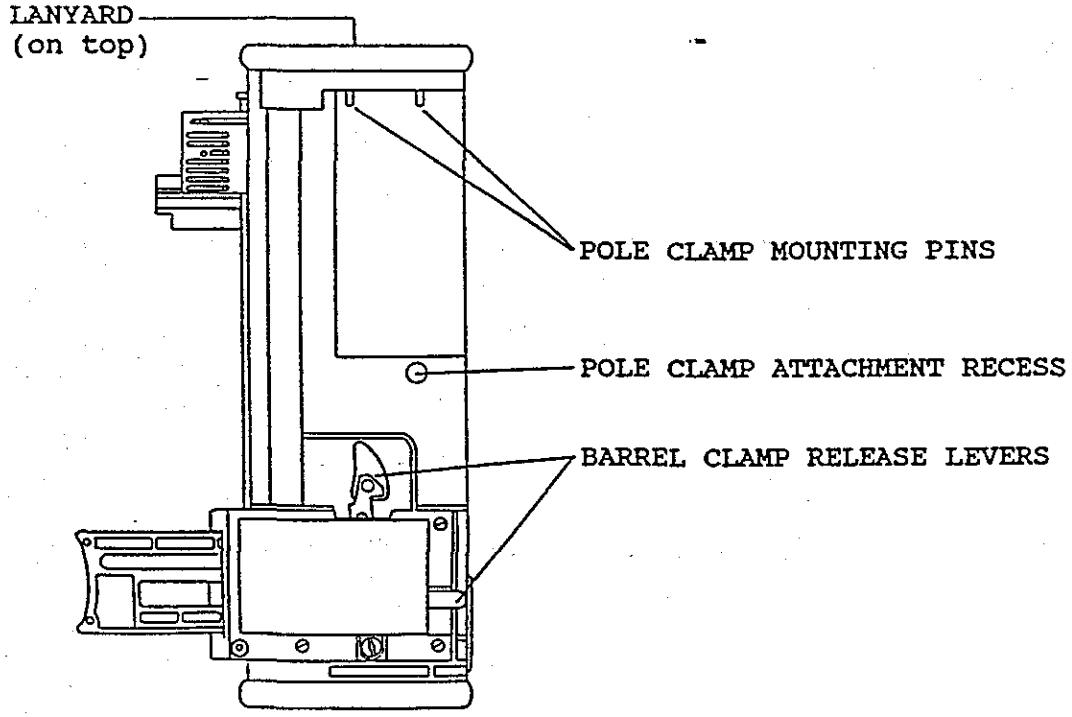
The AS40A is supplied with a pole clamp and a built-in lanyard loop. The pump can also be used as a table-top unit.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CAUTION: Do not perform the procedures described in this manual while the pump is connected to a patient, or in the patient care area.

IMPORTANT: Review the operating instructions carefully before using the AS40A infusion pump.


LCD PANEL
FINGER GRIP
STATUS PANEL
PLUNGER CLAMP
KEYPAD
DRIVER
ON/OFF SWITCH
TAB SLOT
CHARGER PORT
BARREL CLAMP
CRADLE


LANYARD
(on top)
POLE CLAMP MOUNTING PINS
POLE CLAMP ATTACHMENT RECESS
BARREL CLAMP RELEASE LEVERS

Specifications

Size:	approx. 3.4" x 2.6" x 10" (8.6 x 6.7 x 25 cm)
Weight:	approx. 2.75 lbs. (1.25 kg)
Accuracy:	+/- 3% (not including syringe tolerance) +/- .1 mL for bolus infusions < 3 mL (not including syringe tolerance)
Syringes:	B-D Plastipak®, 1, 3, 5, 10, 20, 30, 60 mL Monoject®, 1, 3, 6, 12, 20, 35, 60 mL Terumo®, 1, 3, 5, 10, 20, 30, 60 mL
Deliverable Volume:	See "Syringe Data Tables" section.
Data Display:	Self prompting, multi-field LCD.
Status Display:	Nine LED array.
Power Requirement:	AC: 105-125V 60 Hz (battery charger) DC: internal nickel-cadmium batteries
Battery Life:	12 hours of operation at 2 mL/hr using a 60 mL syringe, following 16 hour charge.
Temperature Range:	0 °C to 45 °C (32 °F to 113 °F) Note: Delivery of very viscous fluids at low temperatures is not recommended.
Keyboard:	Elastomeric type, with tactile feedback.
Construction:	High-impact plastic case with removable elastomeric protective bumpers. Water resistant.

Warnings:

Dose Due
Dose Complete
Pump Is Idle
Editing
Nearly Empty
Low Battery
Near Volume Limit
Attach Charger

Error Responses:

▲▼ in Use
Field Is Open
Out of Range
Keypad Locked
Data Missing
Size Invalid
Load Syringe
Check Syringe

Alarms:

Volume Limit
Line Occluded
Empty

Failsafe Alarms:

Battery
Power Fault
System
Cal Sensors

Configurable Options:

Available Modes
Available Syringe Brands
Available Syringe Sizes
Default to Previous
Occlusion Sensitivity
Auto Lock
Rate Range
Syringe Recognition
Syringe Detection
Volume Limit
Alphanumeric Identifier

Environmental Requirements

Temperature Range:

Operating: 0 °C to 45 °C (32 °F to 113 °F)
Non-operating: -25 °C to 45 °C (-13 °F to 113 °F)
Note: Delivery of viscous fluids at low temperatures is not recommended.

Electromagnetic Susceptibility:

Meets requirements of MDS-201-0004
Meets AAMI #ID-P, "Standards for Infusion Devices"

Electrostatic Discharge Susceptibility:

10 kV, burst mode, direct discharge

Electromagnetic Emissions:

Meets requirements of MDS-201-0004

Product Safety:

Meets requirements of:

UL 544
UL 1310
ANSI/NFPA 99

Environmental Precautions:

DO NOT EXPOSE TO OXYGEN-ENRICHED OR EXPLOSIVE ATMOSPHERES. DO NOT EXPOSE TO IONIZING RADIATION, X-RAY, GAMMA RAY, ELECTROMAGNETIC, OR UV RADIATION. DO NOT STERILIZE.

Syringe Data Tables 7

The following tables represent the performance ranges for those characteristics which are based on the syringe dimensions.

Rate Ranges

Syringe Manufacturer	Syringe Size (mL)	Minimum Rate (mL/hr)	Maximum Rate (mL/hr)
Becton Dickinson®	1	0.01	10
	3	0.02	30
	5	0.03	50
	10	0.1	100
	20	0.1	150
	30	0.1	200
	60	0.1	360
Monoject®	1	0.01	10
	3	0.02	30
	6	0.03	50
	12	0.1	100
	20	0.1	150
	35	0.1	200
	60	0.1	360
Terumo®	1	0.01	10
	3	0.02	30
	5	0.03	50
	10	0.1	100
	20	0.1	150
	30	0.1	200
	60	0.2	360

Note: The "Maximum Rate" information in this table applies to pumps configured for Rate Range = High.

Deliverable Volumes

This table shows the minimum and maximum programmable settings for bolus, volume limit, single dose, and scheduled dose.

Syringe Manufacturer	Syringe Size (mL)	Minimum (mL)	Maximum (mL)
Becton Dickinson®	1	0.03	1.0
	3	0.07	3.0
	5	0.11	5.0
	10	0.3	10
	20	0.4	20
	30	0.5	30
	60	0.8	60
Monoject®	1	0.03	1.0
	3	0.07	3.0
	6	0.11	6.0
	12	0.3	12
	20	0.4	20
	35	0.5	35
	60	0.8	60
Terumo®	1	0.03	1.0
	3	0.07	3.0
	5	0.11	5.0
	10	0.3	10
	20	0.4	20
	30	0.5	30
	60	0.8	60

Purge Delivery

Note: The purge rates shown here are for a pump configured for a Rate Range of "H".

Syringe Manufacturer	Syringe Size (mL)	Approx. Purge Volume (mL)	Purge Rate (mL/hr)
Becton Dickinson®	1	0.02	10.0
	3	0.08	30.0
	5	0.16	50.0
	10	0.23	100
	20	0.39	150
	30	0.50	200
	60	0.76	360
Monoject®	1	0.02	10.0
	3	0.09	30.0
	6	0.17	50.0
	12	0.27	100
	20	0.45	150
	35	0.60	200
	60	0.76	360
Terumo®	1	0.02	10.0
	3	0.09	30.0
	5	0.18	50.0
	10	0.27	100
	20	0.44	150
	30	0.58	200
	60	0.91	360

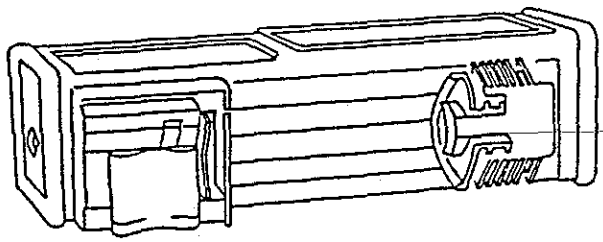
Routine Cleaning

The AS40A should be kept clean at all times. Dirt, sticky films, or foreign substances that are allowed to harden could cause delivery problems.

The AS40A may not be sterilized by autoclave, ETO, gamma ray, or any other method that is harmful to plastic materials or electronic devices.

All exterior surfaces may be cleaned by a mist spray, or by wiping with a damp sponge, nonmetallic brush, swabs, etc. Wipe dry with a soft cloth.

The moving parts may be cleaned by irrigation with warm tap water. Be sure the pump is held in a horizontal position, so the liquid drains out the side of the drive housing and not at the ends.



Notes:

1) The charger plug and power switch areas must be kept clean and dry at all times.

2) Some liquids spilled into the barrel clamp area may temporarily cause excessive "Check Syringe" warnings. Proper operation is generally restored after drying.

3) If routine cleaning does not restore proper operation, the AS40A should be removed from service and given a "service cleaning". This procedure is described in the "Service Procedures" section of this maual.

The exterior surfaces of the pump may be cleaned with any of the following agents:

- Mild, unscented detergent and water.
- Distilled or deionized water followed by hygroscopic rinse to promote drying.
- Dilute isopropyl alcohol (maximum concentration: 15%)
- Dilute ethyl alcohol
- Commercial quartenary ammonium germicidal cleansers, such as Vickers "kleenaseptic®".
- Common commercial cleaners, including:
  - "O-Syl®" (National Laboratories)
  - "Zeptisol®" solution (Calgon Vestal Labs)
  - "Staphene®" aerosol (Calgon Vestal Labs)
  - "Bafix®" aerosol (Hysan Corp.)
  - "Dow Cleaner®" (Dow Chemical)
  - "Steriphene II®" (Spartan Chemical)
  - "Amphyl®" (National Laboratories)
  - "Clorox®" 5% solution
  - "Omega®" and "A3" (Airwick Industries)

Do not use spray solvents or any type of penetrant or penetrating oil.

A "Daily Check" must be completed before returning the pump to service. Perform a "Field Performance Check" if there is any doubt concerning pump operation.

Daily Check

The Daily Check should be performed prior to programming an infusion. There are three steps to the Daily Check: Keypad Check, Mechanical Check, and Lamp Test.

Keypad Check

After the pump completes the power-up sequence, press every key except the <▲> and <▼> arrow keys in any order, one key at a time. Each keypress must result in either one or two short beeps.

Press any two (or more) keys simultaneously. If they are pressed at exactly the same time, there should be no response.

Press and hold any key (except <▲> and <▼>), then press any other key. There should be no response to the second key press.

Mechanical Check

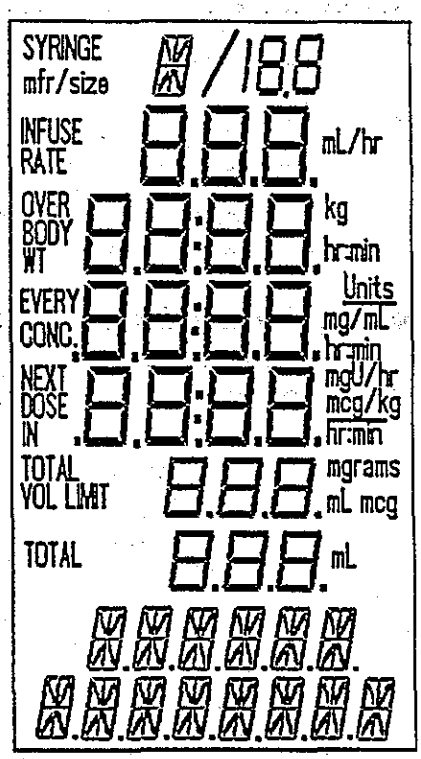
Before using the pump, check for slippage of the driver by applying gentle back pressure. If there is any sign of slippage, take the pump out of service. Raise the finger grip to disengage the drive, and check the driver for free travel through its full range. Check the barrel clamp for free travel and proper locking.

Make sure that the charger plug and socket are clean and that the charger plug can be fully engaged in the socket. When the charger is plugged in, check to be sure the "ON CHARGE" light is on.

Make sure the white rubber pad is in place on the barrel clamp.

Display Check (Lamp Test)

Press and hold the <STOP> key during the normal power-up Lamp Test. This will show the entire display. Compare the display to the illustration. Verify that all annunciators and digits are legible.



Release the <STOP> key to allow the pump to continue the normal power-up process.

Be sure that all lights on the Status Panel illuminate brightly during the Lamp Test.

Notes:

1) If the charger is plugged in, the ON CHARGE light will be on before, during, and after the Lamp Test.

2) If the pump has been dropped or physically damaged in any way, the Display Check must be successfully performed before the pump can be returned to service.

Operate the pump (any mode) for at least 5 minutes, to ensure that all background self-check tasks are executed.

ield Performance Check

The Field Performance Check is a quick check of general AS40A pump performance. For a more complete test, refer to the "Service Procedures" section of this manual.

CAUTION: *Some controls and indicators perform special functions in Calibration Mode. Do not set this mode when pump is connected to a patient, or in patient vicinity.*

CAUTION: *Do not recalibrate the pump during this procedure. If the pump does not perform as described, it must be taken out of service and repaired. Sudden changes in "calibration" may indicate that the pump has been damaged or abused, and is in need of repair or an extensive "service" cleaning.*

Note: *Calibration Mode forces the pump to operate with nonstandard timing. It is not unusual to experience unrecoverable hardware error messages during calibration. If this occurs, the pump must be shut off and then turned back on.*

1) Visual Inspection: look for damage, sticky residue, or other conditions that could affect performance. Clean as necessary. Ensure that the barrel clamp is properly fitted to the case. Check the security of the pole clamp (if used).

) Plug in the charger. The "ON CHARGE" light will illuminate.

3) Do the Lamp Test Check, per user manual: Turn the power switch ON, then press and hold <STOP> during the Lamp Test (when all LCD segments are turned on). Check the display carefully. Ensure that all decimal points and character segments are visible.

4) Release <STOP>, and allow the pump to complete the normal startup sequence. At the [SELECT MODE] prompt message, enter <5089>. This code number sets the pump into Calibration Mode. **The code number should be made available only to authorized service personnel.** The system software revision level will appear for a few seconds, then [DRIVEPOS] will be displayed in the text prompt field. The third and fourth LCD fields will show both raw and processed sensor readings during some calibration steps.

5) Tilt the pump 90 degrees in every axis and note that the ALERT light toggles ON and OFF, depending on the position of the pump.

6) Load a 1 mL syringe. Note that the STANDBY and LOCK lights turn ON when the syringe is properly mounted. Note: this step is especially useful for investigation of repeated [CHECK SYRINGE] warnings.

7) Lift the plunger clamp fully, to allow free movement of the driver. Move the driver slowly from the "syringe full" position to the "syringe empty" position. The numbers displayed on the LCD should change slowly and progressively, with no "dead spots" or other obvious anomalies.

8) Install a 60 mL syringe (from a 1991 or later production lot). Set the syringe plunger at the mid-point (30 mL) mark. Bring the driver face against the syringe thumb press, as if loading the syringe for an infusion. The number in LCD Field #4 (plunger position in inches) should be steady and should read:
   - for B-D 60 mL: [2.798] +/- 0.01
   - for Monoject 60 mL: [2.784] +/- 0.01
   - for Terumo 60 mL: [2.686] +/- 0.01

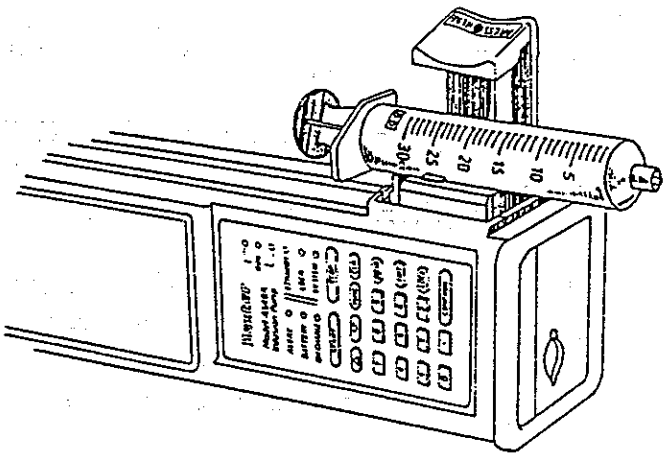
   Note: Some deviation may be the result of syringe scale offset. Try using a syringe from a different lot.

9) Push the syringe plunger to the "empty" position, then bring the driver down until it contacts the face of the syringe thumb press. Field #4 of the LCD should be steady and read:
   - for B-D 60 mL: [.672] +/- .01
   - for Monoject 60 mL: [.660] +/- 0.01
   - for Terumo 60 mL: [.910] +/- 0.01

10) Press <CONFIRM>. The text field will display [CAL DRIVEPOS], and a blinking [Y] will appear in Field #1, on the top line of the LCD. Use the <▲> or <▼> keys to change the [Y] TO [N], and then press <CONFIRM>. The text field will display [SYRNGREC]. Fields #3 and 4 on the LCD will display the raw and processed Syringe Recognition subsystem readouts.

    If the [SYRNGREC] prompt is not displayed, the pump may have been accidentally set into Calibration Mode. Turn the pump off and begin again.

11) Position the pump on its side (syringe mount facing up). Release the barrel clamp to the fully open position, then rest a B-D 30 mL, Monoject 20 mL, or Terumo 20 mL syringe (1991 production year or later) on the syringe cradle.



Hold the barrel clamp release lever in the "open" position, to allow the barrel clamp to slide in and out freely, then gently bring the barrel clamp down until it makes light contact with the syringe barrel.

Gradually increase pressure on the barrel clamp, until the LOCK light illuminates. Note the LCD readouts. At the exact point at which the LOCK light just comes on, field #4 should read as follows:

- B-D = [.7417] +/- .01
- Monoject = [.691] +/- .01
- Terumo = [.663] +/- .01

12) Remove the syringe, and replace it with a B-D 5 mL, Monoject 6 mL, or Terumo 5 mL syringe (1991 or later production year).

Hold the the barrel clamp release lever in the "open" position, and apply gentle clamping pressure, as in the previous step. Note the LCD reading at the exact point at which the LOCK light illuminates. Field #4 should read:

- B-D = [.2909] +/-.01
- Monoject = [.329] +/-.01
- Terumo = [.335] +/-.01

Remove the syringe, then continue to the next step.

13) Press <CONFIRM>. The text field displays [CAL SYRNGREC], and a blinking [Y] appears in Field #1. Extend the driver to "syringe full" position.

USE THE <▲> OR <▼> KEYS TO CHANGE THE [Y] TO [N], and then press <CONFIRM>.

14) The text field displays [PRESSENS], and the pump motor begins to run.

If [PRESSENS] is not displayed, the pump may have been accidentally set into Calibration Mode. Turn the pump power off and repeat the procedure.

After the motor has run about 5 seconds, LCD Field #4 will display the calculated syringe load in pounds. The reading should be approximately [0.00].

The pump motor will continue running. Release the driver and move it to about the "syringe half full" point. Reposition the pump onto its back, so that the LCD is facing up. Note the LCD readings. The calculated load reading should remain close to zero. Some "flicker" from small positive to small negative values is acceptable.

Note: *Failure to obtain the above results may indicate that there is a problem. The pump should be taken out of service and repaired.*

This completes the Field Performance Check.

General Information

The AS40A has two configuration modes, each of which is selected by entering a special access code immediately after the power-up lamp test. Configuration Set Mode allows the pump configuration to be modified. Configuration Review Mode allows for review only, and does not allow the configuration to be changed.

Configurable Options

Available Modes	Limits the number of modes available to the user.
Available Syringe Manufacturers	The pump prompts only for the brands of syringe actually used.
Available Syringe Sizes	The pump limits syringe selection to those sizes actually used.
Default to Previous	The pump defaults to the syringe and delivery mode previously used.
Syringe Recognition	The pump automatically determines the size of the syringe.
Syringe Detection	The pump alarms if the syringe barrel is improperly clamped.
Occlusion Sensitivity	Fine tunes the occlusion alarm by tailoring for the appropriate range of pressures (High, Medium, Low).
Auto Lock	Automatically locks the keyboard when the keyboard becomes idle.
Volume Limit	Available in mL/hr mode only. Sounds an alarm when the Volume Limit counts down from the programmed value to zero.
Rate Range	Limits the maximum delivery rate to High, Medium, or Low range.
Audio Range	Sets the audio to High or Low loudness .
Alphanumeric Identifier	The pump briefly displays a special message when it is turned on.

Configuration Set Procedure

Select "Configuration Set" Mode

To select Configuration Set Mode, turn the pump on and enter <9805> after the Lamp Test. Note that there will be an "Invalid Key" error response for each of these keystrokes. **This code should only be made available to authorized technical personnel.**

Prompting

The text display area prompts for each option. The user response field (the single-character digit in Field #1) shows the response that is pending. The arrow keys (<▲>, <▼>) are used to step through the available choices (Yes, No, High, Medium, or Low). Pressing the <CONFIRM> key locks in the pending selection.

Configuration Sequence

The configurable options are organized into groups, as illustrated below.

GROUP PROMPT	CONFIGURABLE OPTION PROMPT
[SELECT MODES?]	[ML/HR] : [UNITS/HR] : [SINGLE DOSE] [MANUAL SCHEDULE] : [AUTO SCHEDULE] [MCG/MIN] : [MCG/KG/MIN]
[SELECT MFRS?]	[B-D] : [MONOJECT] : [TERUMO]
[SELECT SYRNGES?]	[(n)ML B-D], n = 1, 3, 5, 10, 20, 30, 60 [(n)ML MONOJECT], n= 1, 3, 6, 12, 20, 35, 60 [(n)ML TERUMO], n = 1, 3, 5, 10, 20, 30, 60
[SELECT DFAULTS?]	[MODE DEFAULT] : [MFR DEFAULT] : [SYRING DEFAULT]
[SELECT MISC?]	[SYRING RECOGNIT] : [SYRING DETECT] : [PSI RANGE] [AUDIO RANGE] : [RATE RANGE] : [AUTO LOCK] [VOLUME LIMIT]
[SELECT IDENT?]	Blinking cursor in text field.

The first prompt for each option group is a [SELECT | (group name) ?] query. The default pending response is [Y] (yes). Press <CONFIRM> to begin configuring the group. To skip ahead to the next group, use either arrow key to change the pending response prompt to [N] (no), and then press <CONFIRM>.

Once a group has been opened for configuration, every option within that group must be configured. After the final option within a group has been configured, the display will read [UPDATING] for a few seconds while the pump's configuration memory is updated, and then will display the next [SELECT | (group name) ?] query. The new group configuration is not saved until the [UPDATING] message has been displayed and the next [SELECT | (group name) ?] message appears.

For example:

Following mode configuration, the next prompt is [SELECT MFRS?]. There is a flashing [Y] in the user response field on the top line of the LCD screen.

- Pressing <CONFIRM> begins the process of selecting the available syringe manufacturers. The next display is [MONOJECT].

- Pressing <▲> or <▼> changes the [Y] to [N]. Pressing <CONFIRM> then skips the entire [SELECT MFRS?] group and continues on to the [SELECT SYRNGES?] prompt.

The pump configuration must include at least one mode, manufacturer, and syringe size.

Standard Configuration

The factory standard configuration is:

Modes:	All modes enabled.
Manufacturers:	All syringe manufacturers enabled.
Syringes:	All sizes available.
Defaults:	No defaults enabled.
Misc:	
Syringe Recognition:	Y
Syringe Detection:	Y
PSI Range:	M
Audio Range:	H
Rate Range:	H
Auto Lock:	N
Volume Limit:	Y

Completing the Configuration Process

After the last option group has been configur :d or skipped, the pump terminates the configuration set process by initiating a normal power-up restart.

Aborting the Configuration Process

Configuration information is stored a whole group at a time. If the pump power is turned off before the [UPDATING] message appears, any pending changes will be lost. The group will revert to the previous settings.

Configuring the Modes Group

Initial Prompt: [SELECT | MODES?]

Each mode is prompted by displaying the mode name. The user response field on the top line of the display will show with the current (pending) status. [Y] = mode available to the user. [N] = mode not available to the user. All modes are initially enabled at the factory. At least one mode must be enabled.

Configuring the Manufacturers Group

Initial Prompt: [SELECT | MFRS?]

At least one syringe manufacturer must be configured. The display codes are:

1) [MONOJECT] = Monoject®
2) [B-D] = Becton Dickinson Plastipak®
3) [TERUMO] = Terumo®

Configuring the Syringes Group

Initial Prompt: [SELECT | SYRNGES?]

The text field prompts for each available syringe by showing the nominal syringe size and the manufacturer name, e.g. [1 ML | B-D]. At least one syringe must be selected for each configured manufacturer.

Configuring the Defaults Group

Initial Prompt: [SELECT | DFAULTS?]

When enabled, the Defaults group options simplify user programming by initializing the pump to the mode, manufacturer, and/or syringe size that were used the last time the pump was operated. Three default options are available:

[MODE | DEFAULT]
[MFR | DEFAULT]
[SYRING | DEFAULT]

Configuring the Miscellaneous Group

Initial Prompt: [SELECT | MISC?]

The "Miscellaneous" group includes six options:

[SYRING | RECOGNIT]

Syringe Recognition is a convenience feature that simplifies programming by initializing the "SYRINGE size" field to the size of the syringe that is mounted. Note: enabling this feature automatically enables Syringe Detection. Select [Y] to enable this option, [N] to disable.

[SYRING | DETECT]

Syringe Detection is a safety enhancement that issues an alarm if the syringe is improperly mounted in the barrel clamp. This feature is active while the pump is delivering. Syringe Detection is automatically configured when Syringe Recognition is enabled. It is recommended that Syringe Detection should always be enabled. Select [Y] to enable this option, [N] to disable.

[PSI | RANGE]

Fine tunes the occlusion alarm by tailoring the occlusion detection system to the pressure range most appropriate for the infusion. One of three ranges must be selected:

[H] = high pressure range
[M] = medium pressure range
[L] = low pressure range

The factory standard setting is [M], which is suitable for delivering fluids of about the same lubricity and viscosity as water.

[AUDIO | RANGE]

Sets the audio loudness to [H] (loud) or [L] (quieter). The standard setting is [H]. It is recommended that the [L] setting not be used for unattended pump operations.

[RATE | RANGE]

Limits the maximum fluid delivery rate. The standard setting is [H]. The available settings are:

[H] = 360 mL/hr
[M] = 120 mL/hr
[L] = 15 mL/hr

The rate range setting applies simultaneously to bolus, purge, and maximum delivery rate.

Note that syringe factors also limit the rate range. For example, it is not possible to exceed 10 mL/hr from a 1 mL syringe, regardless of the rate range setting. See Syringe Data Tables, pp. 7-9.

[AUTO | LOCK]

When enabled, Auto Lock automatically activates the Lock feature when the keyboard is idle, two minutes after programming has been completed. This helps prevent tampering and accidental keypresses. The keyboard is manually locked or unlocked by pressing the <LOCK> key. Select [Y] to enable this option, [N] to disable.

[VOLUME | LIMIT]

The Volume Limit option is only available for use in "ML/HR" Mode. When enabled, Volume Limit halts and sounds an alarm when a programmed volume has been delivered. There is also a 10-minute "Near Volume Limit" warning. Select [Y] to enable this option, [N] to disable.

Selecting an Identifier

Initial Prompt: [SELECT | IDENT?]

The Identifier option is an alphanumeric message that is displayed for about three seconds, following the power-up Lamp Test. Select [Y] to create/edit the identifier, [N] to leave the present identifier (if any) unchanged. Since this is the final configuration step, the pump will initiate a normal power-up at the conclusion of this step.

Note that <EDIT> performs a special function that is unique to this operation.

- At the [SELECT | IDENT?] prompt, press <CONFIRM>. The leftmost character (or space) flashes to show that it is "active".
- Use the arrow keys to scroll through the character set, stopping at the desired character.
- The <EDIT> key accepts the displayed character and steps to the next character.
- Use the <CLR> key to clear the current character.
- <CONFIRM> completes the identifier selection process.

Pump Configuration Example

Turn the pump off, then on. At the [SELECT | MODE ▼▲] prompt, press <9805>. Then use <▼> or <▲> as required to set the correct pending response. Use <CONFIRM> to lock in the pending response and move to the next step.

Beginning with the factory standard configuration, reconfigure the AS40A for:

- **MODES: ALL**
- **MODE DEFAULT: N**
- **PSI RANGE: M**
- **AUDIO RANGE: H**
- **VOLUME LIMIT: Y**
- **SYRINGE DETECTION: Y**
- **MFRS: BD ONLY**
- **MFR DEFAULT: N**
- **SYRINGE RECOGNITION: Y**
- **RATE RANGE: H**
- **IDENTIFIER: BD ONLY**
- **SYRINGES: ALL**
- **SYR. DEFAULT: N**
- **AUTO LOCK: N**

NOTE: Underlined items are to be changed from the standard configuration.

TEXT PROMPT	Key Entry	TEXT PROMPT	Key Entry
[SELECT MODES?]	<▲><CONFIRM>	[SELECT MISC?]	<CONFIRM>
[SELECT MFRS?]	<CONFIRM>	[SYRING RECOGNIT]	<CONFIRM>
[B-D]	<CONFIRM>	[PSI RANGE]	<CONFIRM>
[MONOJECT]	<▼><CONFIRM>	[AUDIO RANGE]	<CONFIRM>
[TERUMO]	<▼><CONFIRM>	[RATE RANGE]	<CONFIRM>
[SELECT SYRNGES?]	<▼><CONFIRM>	[AUTO LOCK]	<CONFIRM>
[SELECT DFAULTS?]	<▼><CONFIRM>	[VOLUME LIMIT]	<CONFIRM>
		[SELECT IDENT?]	<CONFIRM>

The far left space of the text display will be flashing. Press <▲> twice, so that a flashing [B] is now displayed. Press <**EDIT**> to move to the next digit. Continue in this way, until the display reads [**BD ONLY**], then press <**CONFIRM**>. The pump will display [**UPDATING**] for a few seconds, then will initiate a normal power-up reset.

Configuration Review

The Configuration Review feature allows the pump configuration to be checked without risk of accidental alteration.

To review the AS40A pump's configuration, enter <123> after the power-up Lamp Test. Ignore the "Invalid Key" beeps that occur while entering this code number. The pump displays the current software revision level in the text field for 3 seconds.

The configuration sequence displays the category being reviewed in the lower screen field, followed by a question mark (for example: [VIEW MODES ?]). The upper screen field displays a [Y] (for "yes").

- Pressing <CONFIRM> begins reviewing the options within this category. The text field will display only the options that are configured. Pressing <CONFIRM> steps to the next option.

- Pressing either <▲> or <▼> changes the [Y] to [N] (for "no"), indicating that review of this category is not wanted. Press <CONFIRM> to advance the screen to the next category for review.

The configuration options are grouped as follows:

[VIEW MODES ?]:
ML/HR, UNITS/HR, SINGLE DOSE, MANUAL SCHEDULE, AUTO SCHEDULE, MCG/MIN, MCG/KG/MIN

[VIEW MFRS ?]:
B-D, MONOJECT, TERUMO

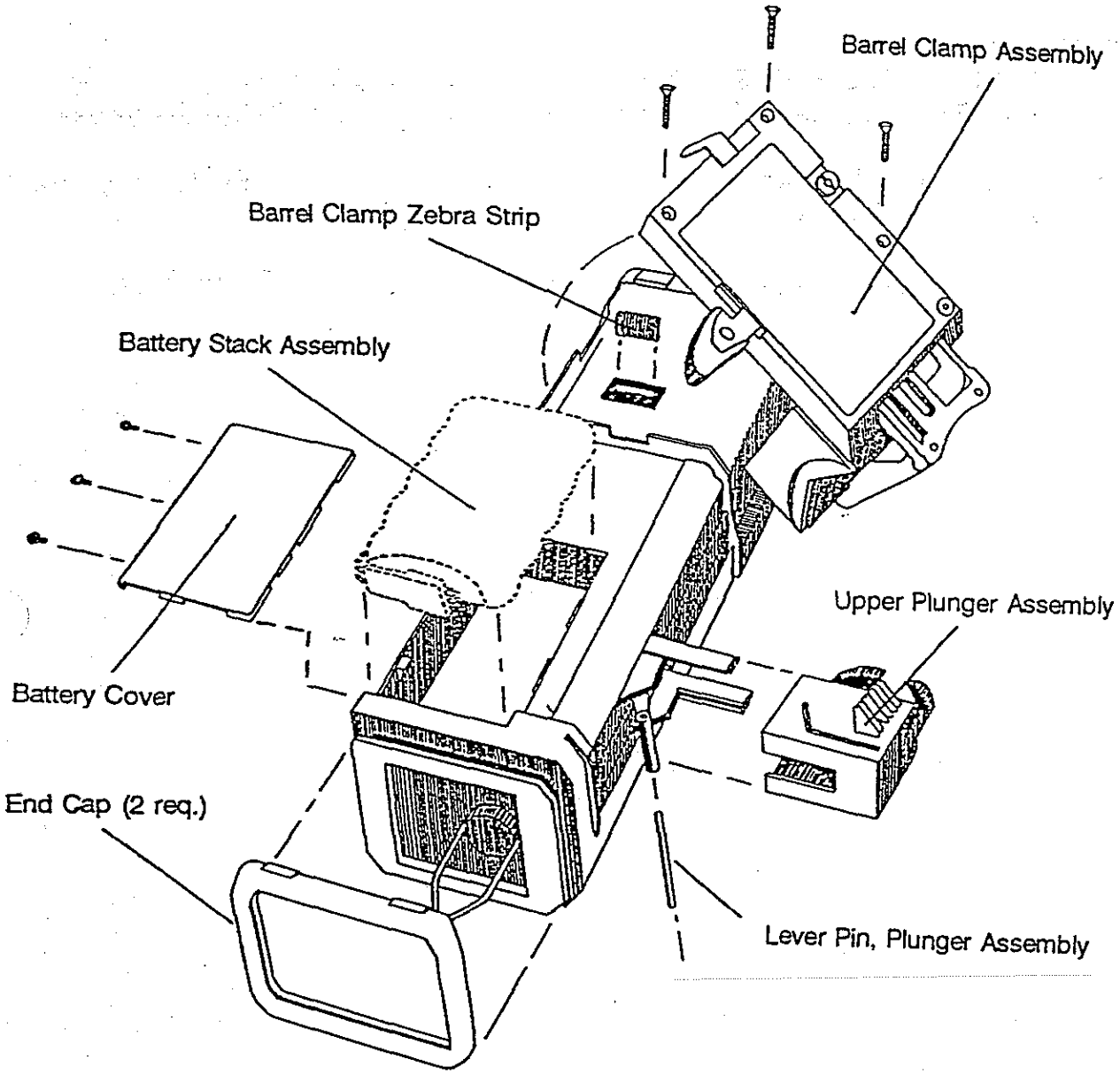
[VIEW SYRNGES?]:
B-D: 1 ML, 3 ML 5 ML, 10 ML, 20 ML, 30 ML, 60 ML
MONOJECT: 1 ML, 3 ML, 6 ML, 12 ML, 20 ML, 35 ML, 60 ML
TERUMO: 1 ML, 3 ML, 5 ML, 10 ML, 20 ML, 30 ML, 60 ML

[VIEW DFAULTS ?]:
MODE DEFAULT, MFR DEFAULT, SYRING DEFAULT

[VIEW MISC ?]:
SYRING RECOGNIT, SYRING DETECT, PSI RANGE (H, M, L), AUDIO RANGE (H, L), RATE RANGE (H, M, L), AUTO LOCK, VOLUME LIMIT

When the last option has been reviewed, the pump automatically restarts the Lamp Test, as if it had just been turned on.

NOTE: To cancel the configuration review at any time, simply turn the pump off.


Barrel Clamp Assembly
Barrel Clamp Zebra Strip
Battery Stack Assembly
Upper Plunger Assembly
Battery Cover
End Cap (2 req.)
Lever Pin, Plunger Assembly

Pump Unit Disassembly

Barrel Clamp Assembly

The barrel clamp assembly is held in position by three screws and a locating boss molded into the case. To remove the barrel clamp, remove the three philips-head screws, then lift and rotate the assembly as shown.

Note that the flexible barrel clamp zebra strip connector fits in a pocket under the barrel clamp. The metallic "zebra strips" must face toward the top of the pump. The zebra strip and the corresponding conductive pads must be perfectly clean before assembly.

Plunger Driver Assembly

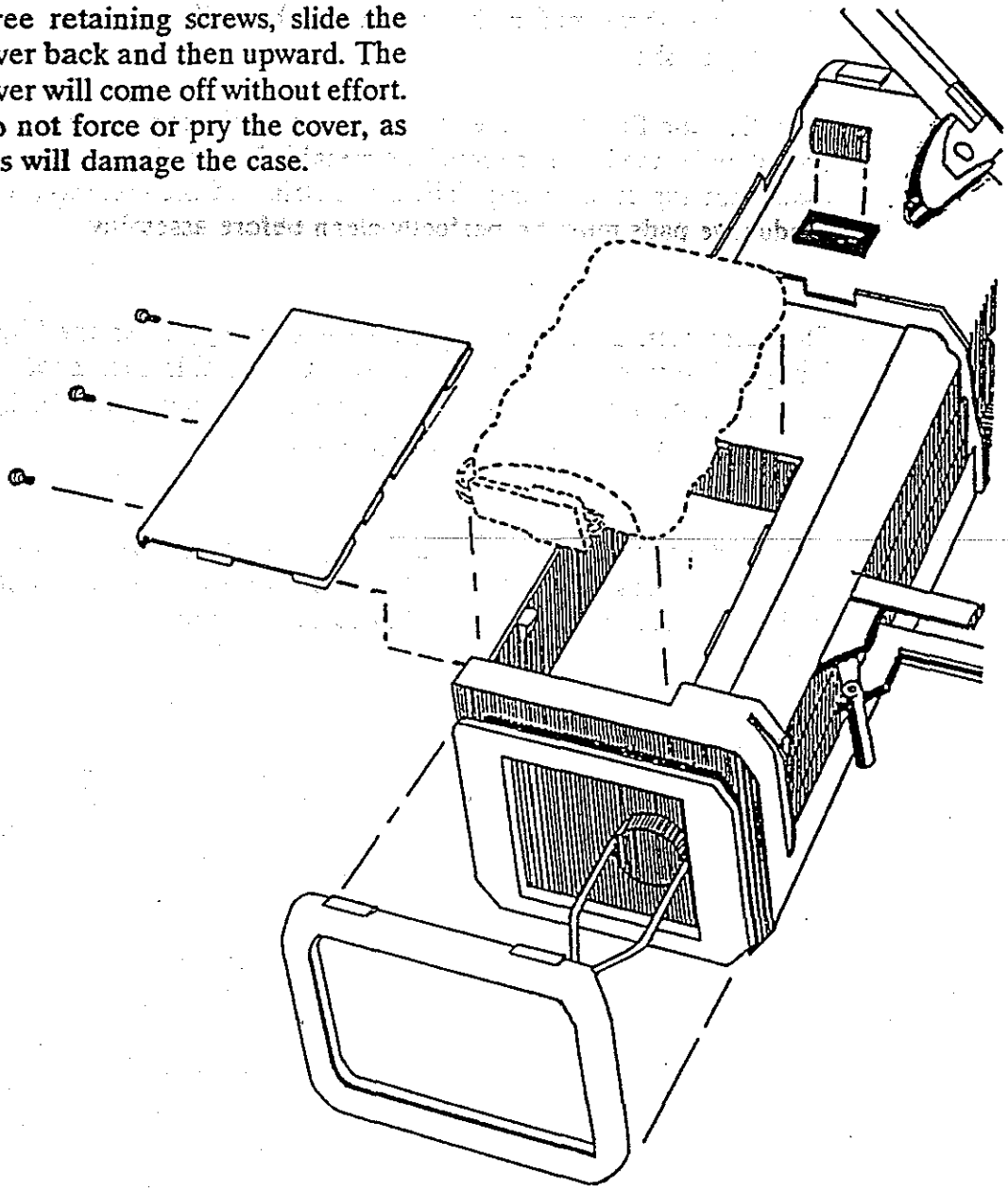
The outer portion of the plunger driver assembly, called the Upper Plunger Assembly, is easily replaced. Use a suitable tool, such as a drift punch or thin rod, to apply *hand pressure* to push out the lever pin, then lift off the outer plunger assembly.

Bumpers (End Caps)

The flexible rubber "bumpers" (End Caps) stretch to fit over flanges built into the case top and bottom. Be sure to install the bumpers so the flat "feet" are toward the back of the pump.

Battery Replacement

The battery pack hatch cover is on the back of the AS40A pump. To remove the cover; remove the three retaining screws, slide the cover back and then upward. The cover will come off without effort. Do not force or pry the cover, as this will damage the case.

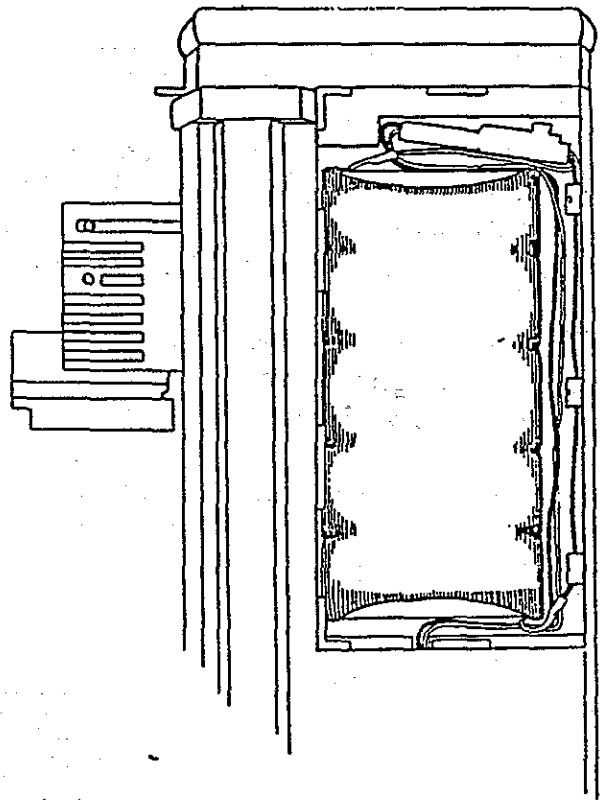


With the cover off, the battery pack can be easily removed from the case. *Do not pry on the battery pack.* Do not allow the pack to fall from the case, as the weight of the hanging battery pack can damage the wire harness.

Disconnect the wire harness at the battery connector. Press the latch tab to release the connector.

The battery pack is cushioned by a foam battery compartment liner. Inspect the foam before replacing the battery pack. The foam must be replaced if it is stained, wet, or damaged.

If the insert is wet, then the pump's moisture seal has been compromised. Remove the foam insert and dry out the pump interior using warm air. Do not allow foreign material to get inside the pump. Keep the warm air temperature below 45°C (113°F).



CAUTION: *When reinstalling the battery pack, be sure the leads are carefully dressed along the sides of the pack (see illustration). Be sure the leads are not crushed or kinked.*

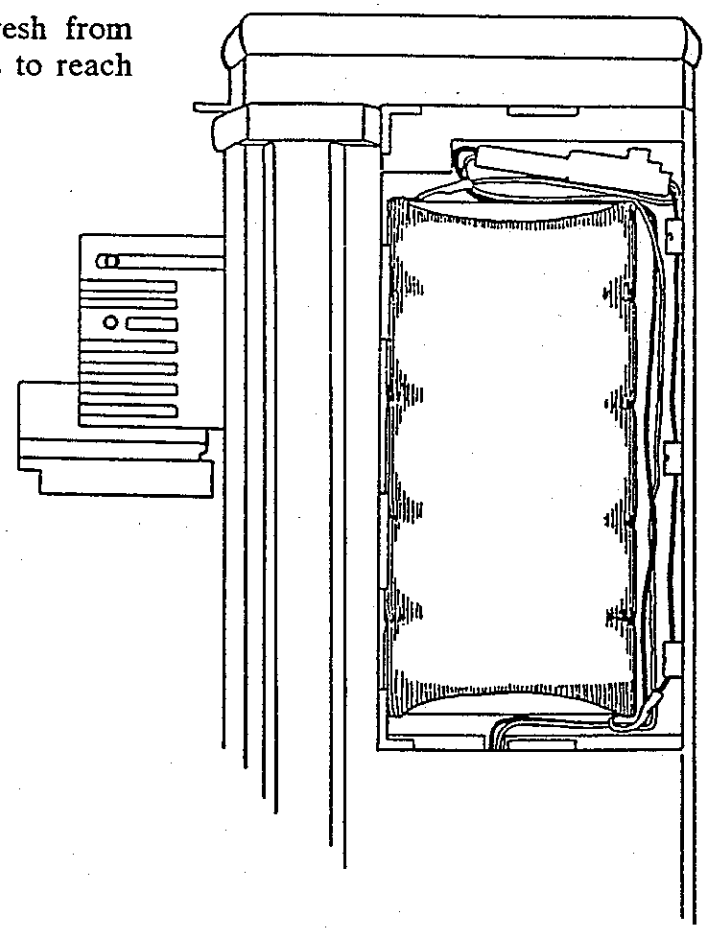
Battery Life Check

The battery pack is considered acceptable when it can operate at 80% capacity or better. Battery capacity can be estimated as follows:

(1) Charge the battery (with the AS40A pump turned off) for at least 24 hours.
(2) Remove the battery pack.(See "Battery Replacement" section)
(3) Connect a 135 ohm, 1/2 watt resistive load across the battery connector.
(4) Continuously monitor the battery voltage and discharge time.

The battery pack is acceptable if the battery voltage is 5V or greater after 19 hours of discharge through a 135 ohm load.

Note that new battery packs, fresh from stock, may take 3-5 charge cycles to reach full operational capacity.



Service Cleaning

The AS40A is designed for easy cleaning in the field, using water-based irrigation. This procedure is described under "Routine Cleaning".

The Service Cleaning procedure is more thorough than the routine cleaning procedure, and is generally advised when the pump has been soaked with a low-viscosity fluid containing conductive, corrosive, or sticky fluids that are not water soluble. Service cleaning should also be considered part of any service operation, especially if the barrel clamp or driver has been serviced. An excessive number of [CHECK SYRINGE] alarms may be a symptom that Service Cleaning is needed.

Barrel Clamp Cleaning

- Remove the three phillips-head screws retaining the barrel clamp.
- Remove the barrel clamp by pivoting about the upper edge of the clamp cradle.
- Liberally irrigate the contaminated surfaces, using a soft-bristled brush to work the solution into all corners and crevices. Open and close the clamp a few times, to help work the cleaning solution into the sliding surfaces.

NOTE: DO NOT IMMERSE THE BARREL CLAMP ASSEMBLY.

- If this does not loosen the dirt, wipe the surface with a sponge and any of the approved cleaning agents listed in the User Manual, followed by a rinse with a 50/50 mixture of water and isopropanol. Do not allow the cleaning agent to leak into the barrel clamp electronics.
- After removing all contamination, blot the assembly dry with a clean paper towel. Air dry overnight at room temperature. Do not use a hair dryer or other hot-air device.
- Before reinstalling the barrel clamp, clean the six electrical contact pads and the mating connector on the pump body, using a lint-free pad and isopropanol. Pivot the barrel clamp assembly into place on the pump, then reinstall the three screws. Tighten the two outer screws first.

Plunger Drive Cleaning

- Irrigate the plunger driver and drive assembly with 50/50 distilled water/isopropyl mixture. DO NOT IMMERSE THE PUMP!

- If the plunger driver cannot be cleaned with irrigation alone, extend the plunger clamp and direct a gentle stream of warm tap water on the driver assembly. Direct the stream carefully, to minimize the water exposure to the pump case.

- Surface contamination can be cleaned by wiping with a sponge and any of the approved cleaning agents listed in the User Manual, followed by a water/ isopropyl rinse. Do not allow detergents to flow into the drive compartment.

- If the drive compartment is contaminated, flush the drive area with warm water. Hold the pump in a horizontal position, so that water runs out the side of the drive area, and not the ends.

- Dry the plunger and drive assembly by blotting, followed by a gentle air stream or overnight free-air drying.

- Do not lubricate any of the drive parts. The AS40A is designed to operate without lubrication.

The pump must successfully complete the Field Performance Check before being returned to service. If there is a problem, the pump must be repaired, recalibrated, and retested.

Note: Because the above procedure requires skill and careful attention to detail, the manufacturer cannot assume responsibility for damage caused by ingress of cleaning agents or other fluids into sensitive areas of the pump.

Calibration Check

The calibration of the AS40A should be checked at least twice a year, and as part of every service operation. The following equipment and materials are needed:

- Complete set of syringes for one manufacturer. All test syringes must be from a current production lot.
- Pressure transducer with readout in psi.
- 60 inch high-flow extension set (1M8521 or eqivalent).
- Pump configuration must include:

Volume Limit:	[Y] (enabled)
Syringe Rec.:	[Y] (enabled)
PSI Range:	[M] (Medium)
RATE Range:	[H] (High)
ML/HR Mode:	[Y] (enabled)
Syringe mfr/sizes:	all syringe sizes for the selected manufacturer must be enabled.

Calibration Check Procedure:

1) Select any syringe, and set the plunger to about the 3/4 full mark.
2) Load the syringe onto the pump, and program an ML/HR infusion for the selected syringe.

- **The pump should recognize the syringe size.**

3) Program the infusion for the maximum rate (e.g. enter a rate of <999> mL/hr, and then <CONFIRM> the corrected rate that the pump displays). Allow the "infusion" to run to completion.

- **The infusion should stop with an [EMPTY] message.**

Note: If [LINE OCCLUDED] occurs before [EMPTY], repeat the test with another syringe from a different (post-1991) production lot. The problem may be due to normal syringe manufacturer's dimensional tolerances.

4) Turn the pump off and remove the syringe.

a) Turn the pump on. Select and mount a syringe. Use very firm pressure when mounting it in the barrel clamp.
b) Set ML/HR mode, and verify that the syringe size is correctly recognized.
c) Turn pump off, remove syringe, and remount with less clamping force than would normally be used. Verify proper size recognition as in the previous step.
d) Repeat the above steps for each of the remaining syringe sizes. Mount each syringe twice, once with very firm clamping pressure and once with light pressure.

► **Verify that the syringe size has been correctly recognized.**

5) Fill a 60 mL syringe half full with water and mount on the pump. Attach to a pressure gauge, using a high-flow extension set. Carefully purge all air from the setup.

6) Program a ML/HR mode infusion of 360 mL/hr. Set Volume Limit to 60 mL.

7) Begin infusing and note the pressure when the [LINE OCCLUDED] alarm occurs.

► **The occlusion pressure reading should be about 13 (+/-3) psi for B-D and Monoject syringes, and about 11.5 (+/-3) psi for Terumo.**

8) Repeat steps 5-7 above, except use a completely filled 1 mL syringe, and a delivery rate of 10 mL/hr.

►**The occlusion pressure reading should be between 14.5 and 38.5 psi.**

Calibration Procedure

The AS40A calibration procedure sets the proper operation points for three parameters:

- Syringe "Empty" point.
- Syringe size and barrel clamp engagement.
- Occlusion pressure detection.

There is no specific calibration interval for the AS40A, except that the zero-load force point should be checked every 6 months and calibrated every 12 months. Any sudden "drift" in the pump's calibration should be considered a symptom that the pump has been damaged. The pump should be removed from service, cleaned, and checked thoroughly.

The AS40A must be recalibrated after any service procedure involving removal of parts.

Equipment and materials needed:

- 1 mL syringe (B-D®, Monoject®, or Terumo®).
- Test Fixture Set:
  - Barrel clamp calibration fixtures CAS40-XX-801; -XX- = -01- to -06-
  - Load Yoke #CAS40-01-802
- Misc.: cable, weights, IV pole

UAS # 1003421
KIT # AAS 4001803
#257.15
need 10 lb. weight

Notes:

1) Read the entire procedure before beginning pump calibration.

2) If results seem to be getting worse during the calibration procedure, simply shut the pump off, review the procedure, and start over.

3) To avoid accidental alteration of calibration settings, do not press <CONFIRM> until the procedure explicitly calls for this action.

4) To skip a section of the procedure, change the "group" prompt from the default [Y] to a [N] by pressing one of the arrow keys. Then press <CONFIRM>.

5) The zero-load force point calibration can be performed without first going through the 10-pound load calibration procedure. This is done by entering <0> in response to the [VERIFY 10.0 LB] prompt. The display jumps directly to the [VERIFY 0.00 LB] procedure, and retains the remaining settings.

6) To do only the zero-load force point calibration, follow the display prompts to skip the [DRIVEPOS] and [SYRNGREC] calibration sections, then go to step #21. The keypress sequence begins by turning on the pump, followed by: <5089> <CONFIRM> <N> <CONFIRM> <CONFIRM> <N> <CONFIRM> <CONFIRM> <CONFIRM>, then proceed to step #21.

Procedure:

1) Begin with a fully charged battery pack, and leave the charger connected throughout the procedure.

2) Turn on the pump. At the [SELECT MODE] prompt and enter <5089>. This code should be made available only to authorized service personnel. The LCD will briefly display the software revision level, then will display a [DRIVEPOS] prompt message. LCD Fields #3 and #4 will show the raw detector (A-D) output and the processed result, respectively. The processed number represents the distance (in inches) between the cradle surface and the driver face.

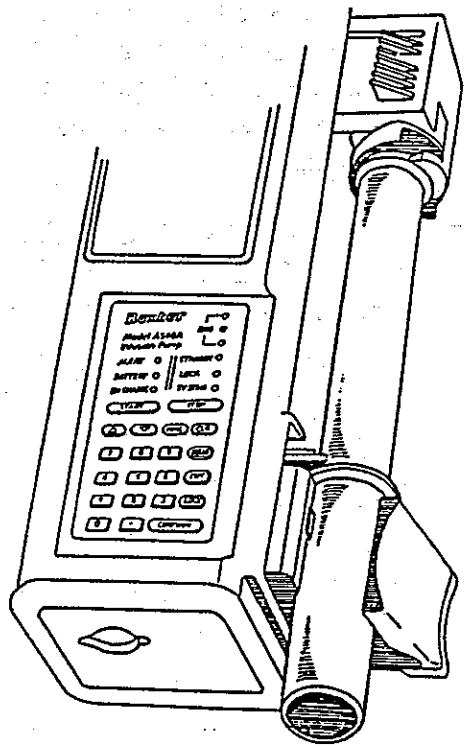
3) Rotate the pump about all three axes. The ALERT light illuminates when the pump is moved from horizontal to vertical.

4) Mount a B-D, Monoject, or Terumo 1 mL syringe in the barrel clamp. Verify that both the STANDBY and LOCK lights turn on. In Calibration Mode, these lights indicate that the syringe tab has been detected, and that the barrel has been sensed.

5) Raise the finger grip, then slowly move the driver back and forth through its full range of travel. Watch the LCD readout while doing so. Both data displays should change in a continuous, linear manner. The numbers should increase as the driver moves in the "syringe full" direction.

6) Press <CONFIRM>. The display will read [CAL DRIVEPOS], and prompt with a flashing [Y] in field #1. Press <CONFIRM> to initiate the drive position calibration sequence. The display will read [VERIFY 2.798]. Install Fixture CAS40-01-801 as though it were a syringe. Be sure the driver is brought into good contact with the fixture flange, so that an accurate measurement can be obtained.

7) Press <CONFIRM>. The 2.798 inch measurement will be recorded, and the display will change to [VERIFY 0.672]. Install Fixture CAS40-02-801 as in the previous step, and press <CONFIRM>.



8) LCD Fields #3 and 4 will show the raw (A/D) and processed readings that correspond to the distance from the syringe tab face to the plunger driver face. Calibration is verified by noting that Fixture CAS40-02-801 reads out in Field #4 as [.672] (+/- .006) inches.

9) Back check the calibration by reinstalling Fixture CAS40-01-801. The Field #4 readout should be [2.798] (+/- .006).

Press <CONFIRM> to complete the Drive Position calibration. The display will read [UPDATING] for a few seconds, while the new calibration information is being saved.

Notes:

a) If the "back check" result in Step 9 does not fall within the stated tolerance, then the pump should be carefully checked for mechanical problems. *Do not continue the calibration procedure until the "back check" is successful.*

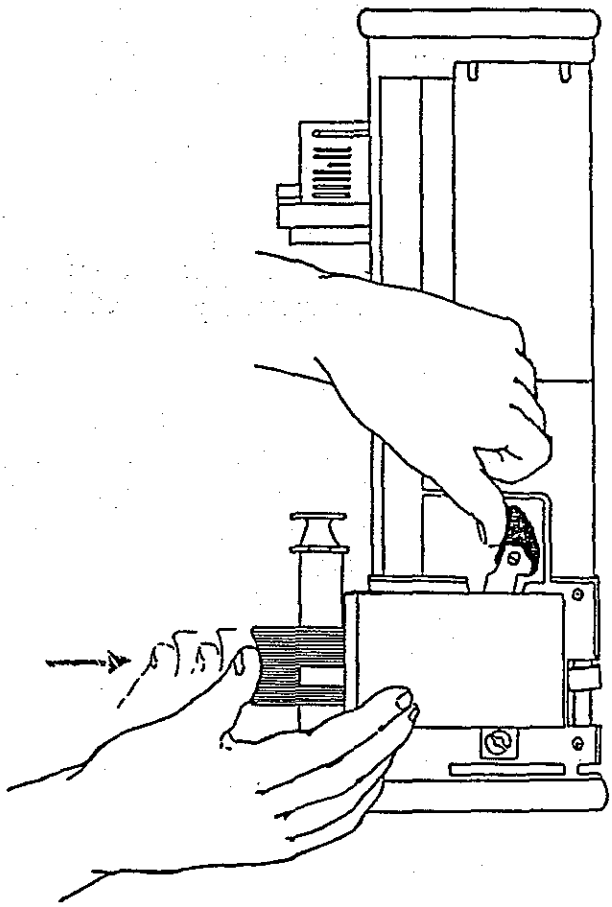
b) If there is a problem, the Drive Position calibration can be aborted by turning the pump power switch OFF at any time prior to display of the [UPDATING] message.

10) The next step is to calibrate the Syringe Recognition system. After completing step (9) above, the display reads [SYRNGREC]. Fields #3 and #4 show raw and converted output, respectively.

11) Hold down the clamp release lever, and move the barrel clamp in and out slowly. The output readings should change in a continuous, linear manner. The readings should show a smaller number as the clamp is pushed in. If discontinuities, "flat spots", or "holes" are observed, the pump must be taken out of service and repaired.

12) Press <CONFIRM>. The display will read [CAL SYRNGREC], and a [Y] prompt will appear in Field #1. Press <CONFIRM> to begin the syringe recognition system calibration. The text display will read [VERIFY 0.742 IN], and a number will appear in LCD field #3.

13) Position the pump on the power switch side, so that the syringe drive faces upward. Gently set fixture CAS40-03-801 in the cradle. Be careful to center the fixture. Do not apply pressure.



Notes:

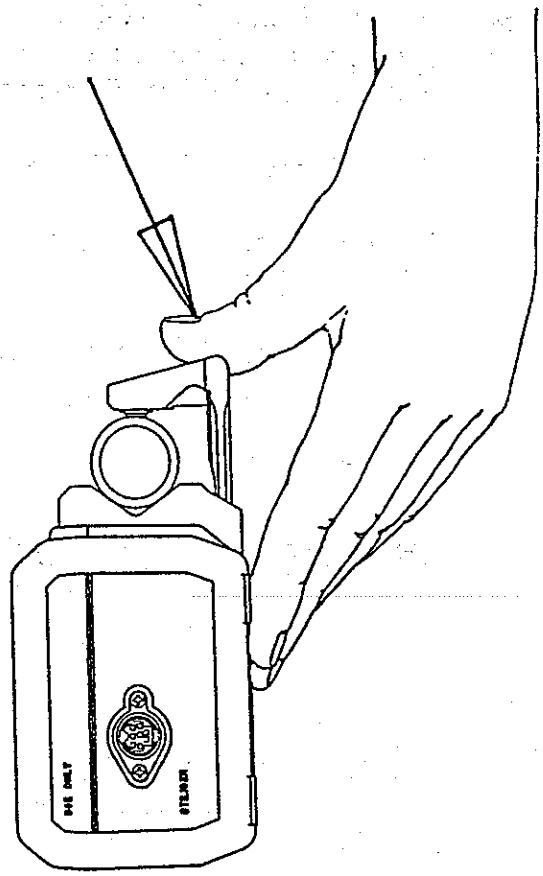
1) In the following steps, the <CONFIRM> key is used to "arm" the measurement subsystem, which then "fires" (records the measurement) when the Syringe Detection cradle switches close. There is no audible indication when <CONFIRM> is pressed.

2) The syringe support system is relatively compliant, and the measurement system is very sensitive. A certain amount of practice will be required in order to obtain consistent results.

14) Press <CONFIRM> to "arm" the Syringe Recognition measurement system.

Bring the barrel clamp slowly in toward the fixture until the clamp very lightly contacts the fixture.

Smoothly and slowly apply increasing thumb pressure inward and slightly to the rear, as shown in the illustration, until the pump beeps.



15) In a few seconds, the text display changes to read [VERIFY 0.291 IN]. Open the barrel clamp fully, remove the fixture (CAS40-03-801), and place Fixture CAS40-04-801 in the cradle.

16) Repeat Step (14) to obtain the "0.291" inch reading. After the pump beeps, the LCD will begin displaying the barrel clamp position in both unconverted and converted units (inches).

Do NOT press <CONFIRM>.

17) Check the calibration by reinstalling Fixture CAS40-03-801. Hold down the barrel clamp release lever, to allow the clamp to slide in and out freely. Observe the LCD display reading (Field #4) while gradually increasing clamping pressure. Note the display at the exact pressure that makes the LOCK light comes on. The reading should be [.742] (+/- .01).

Do NOT press <CONFIRM>.

If the displayed value is not within tolerance, shut off the pump and repeat the calibration procedure.

18) Reinstall Fixture CAS40-04-801. Using the same procedure as for the previous setup, apply gradual clamping pressure and note the reading at the exact pressure that first makes the LOCK light illuminate. The correct reading is [.291] (+/- .01).

Do NOT press <CONFIRM>.

If the displayed value is not within tolerance, shut off the pump and repeat the calibration procedure.

19) Remove the fixture from the cradle and close the barrel clamp completely. Position the driver at least 1/3 of the way up from the end of travel.

Press <CONFIRM> to save the new calibration settings.

The display will read [UPDATING] while the new calibration information is being stored. The next display is [PRESSENS].

This completes the Syringe Recognition portion of the calibration procedure.

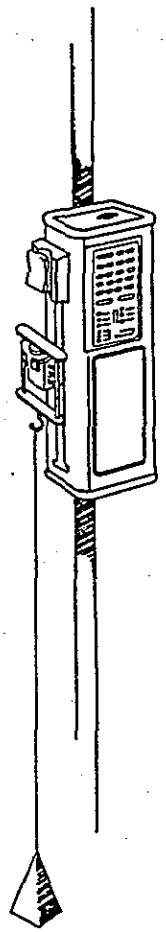
)0) The pump motor begins to run immediately upon completion of the Syringe Recognition calibration procedure. After about 5 seconds, Field #4 begins to display the calculated load against the plunger driver.

Press <CONFIRM>. The motor will stop and the text field will display [CAL PRESSENS]. The Field #1 text prompt will flash [Y].

21) Press <CONFIRM>. The text field will prompt with [VERIFY 10.00 lb].

- To perform the full pressure sense calibration, go to step 22.
- To skip directly to the "zero force" calibration, press <0>. The display will change to [VERIFY 0.00 LB]. Go to step 23.

22) (10 lb. calibration) See illustration. Mount the pump upside down on a vertical IV pole, so that the pump is at least 4 feet above the floor. Assemble the load yoke p/n CAS40-01-802, approx. 3 ft. of cable, and sufficient additional weight to bring the total fixture weight to 10 pounds. Ensure that the driver still has about 1/3 of travel range remaining.



Install the weight/yoke fixture on the driver, and stop any swinging of the weight. Press <CONFIRM>. The display will read [VERIFY 10.0 LB]. Press <CONFIRM> to begin the procedure. The motor will run for about 15 seconds. After the motor stops, the display will read [VERIFY 0.00 LB].

Remove the weight/yoke test fixture. Remove the pump from the IV pole.

23) (0 lb calibration) Lay the pump horizontally on a smooth, level surface. The LCD should be facing up. Ensure that nothing will touch the driver.

Press <CONFIRM>. The pump motor will start running. A reference number between 30 and 100 will be displayed in a few seconds. After a few more seconds, the text field will read [PRESSENS] and a number close to zero will appear in Field #4.

If the average reading is [0.00], then press <CONFIRM> to save the calibration data. This completes the sensor calibration procedure.

Notes:

1) A certain amount of "bit flicker" is inevitable.

2) If the average zero-load reading is significantly different from [0.00], then shut the pump off and repeat the [PRESSENS] calibration procedure.

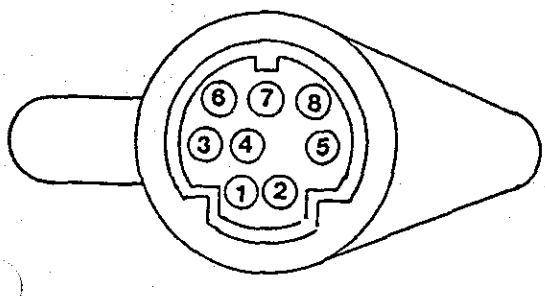
3) The "Calibration Check" procedure should be performed following unit calibration.

The AS40A can only be used with the "900 Series" of chargers and other approved devices.

The standard charger, p/n CAS40-01-900 is rated at:

AC input: 115 VAC, 125 mA, 60 Hz

Output: 8 pin MINI-DIN type. See figure below.



Pin #	Signal Name/Description
0	Shield
1	Charger (+) to Pump
2	Data To Pump
3	Data From Pump
4	Control From Pump
5	Control To Pump
6	Factory Use Only
7	On-Line
8	Charger (-) Output

Rubber Bumpers

The protective end caps ("bumpers") are fitted to the top and bottom of the pump. Replacement bumpers are available in a number of colors, and are packaged in "kits" consisting of two end caps and an installation instruction sheet.

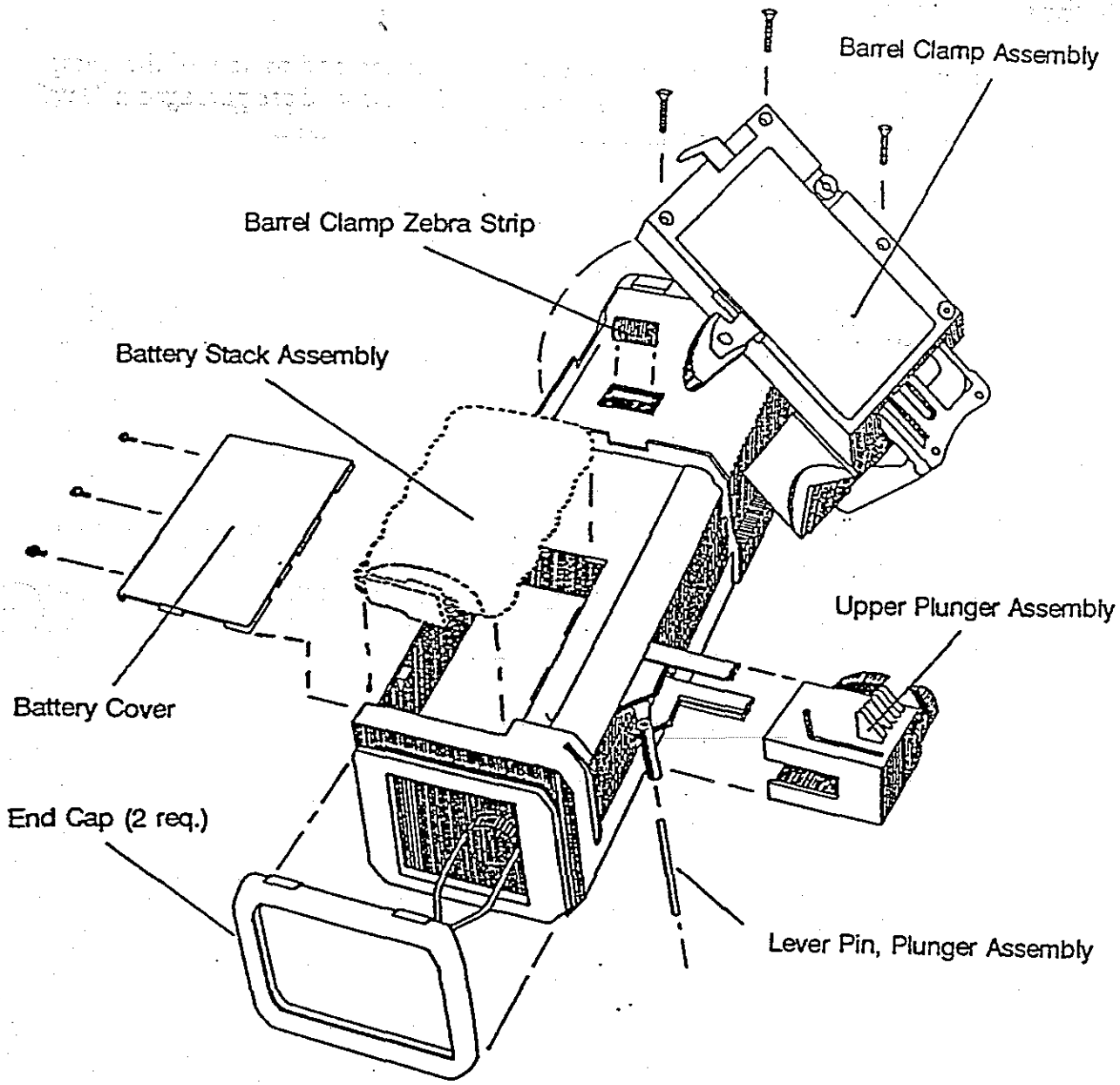
Colored Bumper Kit part numbers:

AAS40-01-491 Grey (Standard)
AAS40-02-491 Blue
AAS40-03-491 Green
AAS40-04-491 Orange
AAS40-05-491 Black

Pole Clamp

The pole clamp can be adapted to allow mounting the pump on a horizontal pole. To adapt the pole clamp, first remove the pole clamp from the pump. Remove the screw on the back side of the pole clamp. Remove the jaw portion of the pole clamp, rotate 90 degrees and replace. Note that it is notched to fit the housing properly. Tighten the screw. and reinstall the pole clamp.

Part Number: A-AS40-01-515


Barrel Clamp Assembly
Barrel Clamp Zebra Strip
Battery Stack Assembly
Upper Plunger Assembly
Battery Cover
End Cap (2 req.)
Lever Pin, Plunger Assembly

Part Name	Part Number
Barrel Clamp Assembly (Requires Barrel Clamp Label p/n BAS40-01-038)	AAS40-01-518
Upper Plunger Assembly (Requires Upper Plunger Assembly Label p/n BAS40-01-012)	AAS40-01-501
End Cap (Bumper) Available as kits only. See "Accessories" section.	AAS40-0X-491 (X = color)
Battery Cover	DAS40-01-483
Battery Cover Screws (3 req.)	S0232-03-663
Battery Stack Assembly	AAS40-01-533
Barrel Clamp Zebra Strip	BAS40-01-487
Barrel Clamp Assembly Screws (3 req.)	S0440-08-614
Lever Pin, Plunger Assembly	BAS40-01-422
Barrel Clamp Label	BAS40-01-038
Upper Plunger Assembly Label	BAS40-01-012

AAS4001531 Top Case

DAS4001615 Back Case

BAS 4001 040 Back Case Label 1011293

Priorities

All error conditions, warnings, and alarms are prioritized. If multiple simultaneous alarms occur, they will be displayed and/or serviced by priority.

Error Responses

The AS40A generally responds to operator error with an "Invalid Key" warning. In certain circumstances, an invalid key press will result in one of the additional responses described below.

Out of Range

If the operator attempts to enter data outside the currently acceptable range, the pump will beep, and the text field will display [OUT OF | RANGE] for 1 second. The nearest acceptable value will then be displayed in place of the incorrect data.

Keypad Locked

If a key is pressed while the <LOCK> function is active, the text field will display [KEYPAD | LOCKED] for 1 second.

▼▲ in Use

Attempting to enter data with the digit keys when the system expects an arrow key to be used will result in a [▼▲ IN USE] display.

Field is Open

Attempting to <START> any delivery during data entry or editing will cause a [FIELD | IS OPEN] display. The <START> key will otherwise be ignored.

Data Missing

Attempting to <START> an unprogrammed bolus will cause a [DATA | MISSING] display. The <START> key will otherwise be ignored.

Load Syringe

Attempting to <START> an infusion without a syringe in place will result in a [LOAD | SYRINGE] message. The <START> key will otherwise be ignored.

Size Invalid

When [SIZE | INVALID] appears during programming, it indicates that the programmed syringe size does not match the detected syringe size. The data in the syringe size field will remain flashing until the situation is resolved.

Check Syringe

If the syringe is not properly mounted when motor movement is commanded, a [CHECK | SYRINGE] message is displayed and the pump beeps once. If [CHECK | SYRINGE] occurs while infusing, the pump beeps continuously. See "Alarms" section. Motor movement is suspended until the situation is corrected.

Warnings

Pump is Idle

The "Pump is Idle" warning occurs when there are no keystrokes (in Standby state) for a period of time. A signal of fifteen short beeps sounds every two minutes and the text field displays [PUMP | IS IDLE] until there is a key press. The ALERT LED will flash during the audio portion of the warning.

Pressing <LOCK> defeats the audio portion of this warning.

Size Invalid

If the detected syringe size doesn't match the programmed syringe size at a time when motor movement is commanded, the pump will sound a single beep and display [SIZE | INVALID]. The operator must either reprogram the syringe size or override the syringe recognition device in order to continue.

Note that this warning could be indicative of a hardware fault, or that a syringe manufacturer has made a dimensional change. Delivery errors could occur if the syringe dimensions have been changed.

An override procedure has been provided to temporarily override this warning in an emergency situation. To override, the operator must first confirm the programmed syringe size. Then, the pump will open each field in succession to force operator confirmation or reprogramming.

Nearly Empty

This warning is issued when there are about 10 minutes of delivery remaining until the syringe empties.

The ALERT LED will flash while the text field displays [NEARLY | EMPTY] for a few seconds. Any keypress silences the audio.

During delivery, the ALERT LED flashes and [NEARLY | EMPTY] is displayed every 30 seconds until a filled syringe is installed or an [| EMPTY] alarm occurs.

Low Battery

This warning is issued when a low battery voltage condition persists for 5 minutes. The **BATTERY** LED will flash and the audio will sound 10 long beeps every 15 minutes. If a low battery voltage condition is detected on power up, the warning will be issued immediately.

Any key press temporarily cancels the audio.

If the charger is not connected, the system will also display [**ATTACH | CHARGER**] each time the beeper is activated.

This warning terminates itself after the battery voltage rises and remains above the low battery voltage threshold for 15 minutes.

Near Volume Limit

This warning can only occur in "mL/hr" Mode, and when the Volume Limit option has been enabled. When the programmed volume limit will be reached in ten minutes or less, the pump will sound 15 short beeps and will display [**NEAR | VOL LIM**] for 5 seconds. The **ALERT** LED will flash during the text display. Any key press aborts the audio.

As the delivery continues, [**NEAR | VOL LIM**] is displayed every 30 seconds until a Volume Limit alarm occurs. The **ALERT** LED will flash during the text display.

Alarms

Dose Due

In Manual Schedule mode, a Dose Due alarm occurs when the NEXT DOSE IN field reaches [0:00].

This alarm puts the pump in Standby state, sounds continuous short beeps, flashes the ALERT LED, and displays [DOSE | DUE]. Any key press silences the audio and shuts off the ALERT LED.

The alarm is reset when the operator presses the <START> key to begin a dose, or if INFUSE, OVER, or NEXT DOSE IN is reprogrammed.

Dose Complete

This alarm is used in Single Dose mode, to alert the operator that the programmed dose has been delivered.

The "Dose Complete" alarm returns the pump to Standby state, issues one short beep every second, flashes the ALERT LED, and displays [DOSE | COMPLETE]. Any key cancels the LED and the audio.

Empty

This alarm occurs when the syringe is empty.

The "Empty" alarm returns the pump to Standby state, sounds continuous short beeps, flashes the ALERT LED, and displays [| EMPTY]. Any key cancels the alarm.

Line Occluded

This alarm is issued when a high pressure condition is detected.

The pump is returned to Standby state, the audio beeps continuously, the ALERT LED flashes, and the text field displays [LINE | OCCLUDED]. Any key cancels the alarm.

Check Syringe

This alarm is issued when an improperly mounted syringe condition is detected during a purge, bolus, or in Run/Delivering state.

The pump is returned to Standby state, the audio beeps continuously, the ALERT LED flashes, and [CHECK | SYRINGE] is displayed. Any key cancels the alarm and leaves the pump in Standby state.

Volume Limit

This alarm only occurs in "mL/hr" mode, when the VOL LIMIT feature has been enabled and the field has counted down to zero.

The alarm returns the pump to Standby state, the audio sounds continuous short beeps, the ALERT LED flashes, and the text field displays [VOLUME | LIMIT]. Any keypress cancels the audio.

The VOL LIMIT field is reset when the <START> key is pressed to initiate a bolus or to enter Run state.

Editing

Some fields (e.g. DOSE, RATE) can be edited in Run state. If one of these is modified but left open, an [EDITING] alarm is issued. The audio sounds continuous short beeps, the ALERT LED flashes, and the text field displays [EDITING]. Any keypress temporarily cancels the alarm. The alarm can only be cleared by completing the edit operation.

Failsafe Alarms

Failsafe alarms occur when the pump detects a serious error. These alarms cannot be canceled, as program data security cannot be guaranteed under Failsafe error conditions. The pump must be shut off and turned back on to recover from these alarms.

Bad Battery

This alarm occurs when the battery charge is depleted. The BATTERY LED is illuminated and an alternating, two-pitch continuous audio signal is sounded.

Power Fault

This alarm is issued immediately when a high battery voltage condition is detected. The BATTERY LED is illuminated and an alternating, two-pitch continuous audio signal will sound. The text field displays [POWER | FAULT].

System

This alarm is issued when an internal error is detected. The SYSTEM LED is illuminated and an alternating, two-pitch continuous audio signal is sounded. The upper and lower lines of the text field will generally display failsafe error information.

General

The mission of a syringe infusion pump is to provide a controlled flow of drug from a syringe. The Model AS40A accomplishes this task by capturing the syringe barrel, and then moving the syringe plunger with a lead screw, driven by an electric motor. The intended drug flow is directed by a user-programmed infusion regimen. There are numerous electrical, mechanical, and software safeguards that ensure safety and effectiveness of operation. The AS40A is powered by internal, rechargeable batteries. The battery pack can be recharged from an external charger while the pump unit is operational.

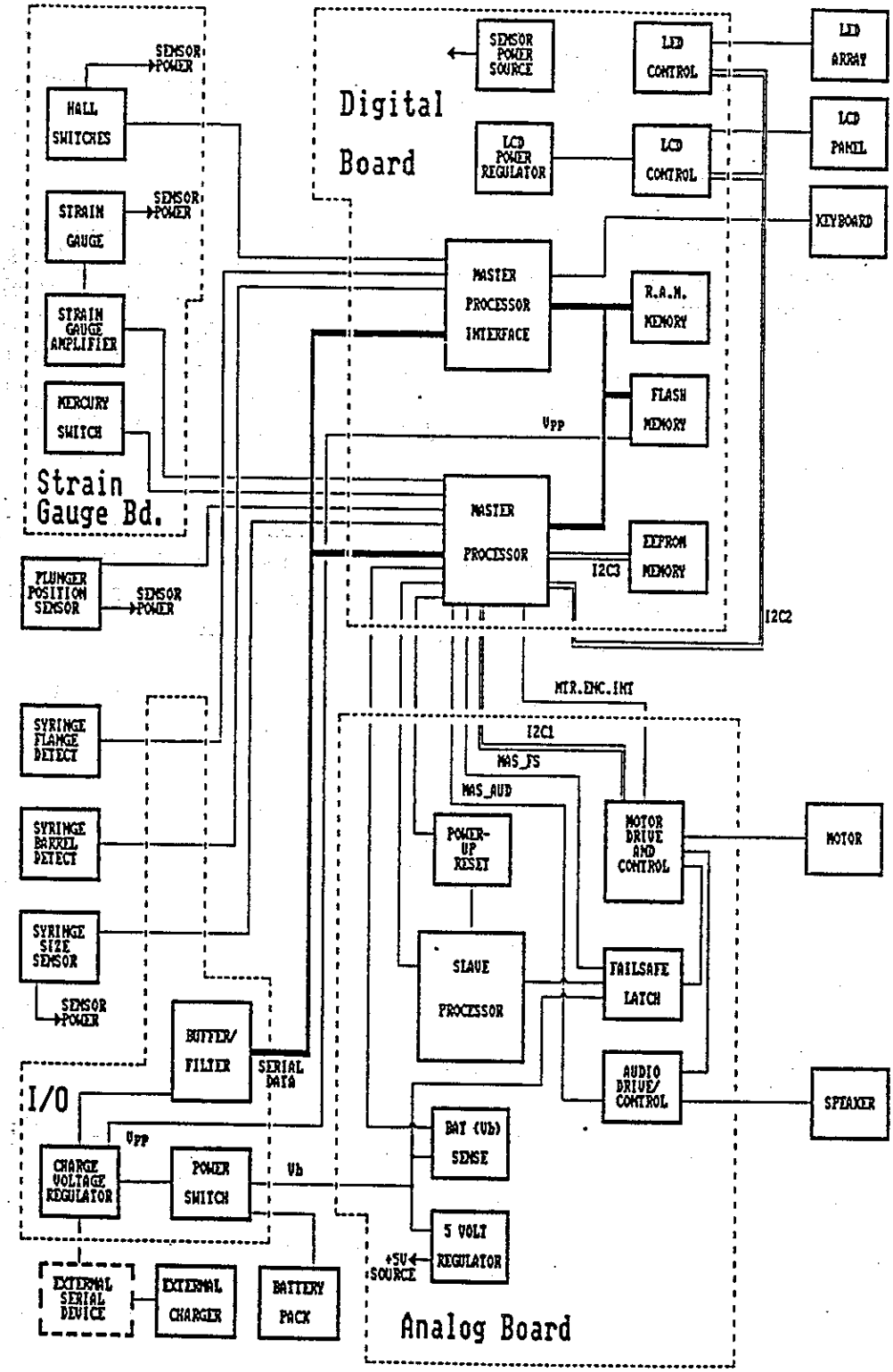
Master/Slave processors, multiple error detection paths, and redundant control paths are used to detect and prevent incorrect pump operation. When a "failsafe" condition is detected, redundant hardware and software controls are engaged to assure that the pump will be forced into a specific (no-delivery) state.

The general aspects of the AS40A design can be divided into the following categories:

- Syringe Retention
- Plunger Control (mechanical)
- Drive Control (electronic)
- User Interface
- Control Subsystems
- Power Supply
- Software

Syringe Retention

The syringe is retained in a clamping device that simultaneously captures both the barrel and the flange.


Digital
Board
Strain
Gauge Bd.
I/O
Analog Board
SENSOR POWER SOURCE
LED CONTROL
LED ARRAY
LCD POWER REGULATOR
LCD CONTROL
LCD PANEL
KEYBOARD
HALL SWITCHES
SENSOR POWER
STRAIN GAUGE
SENSOR POWER
STRAIN GAUGE AMPLIFIER
MERCURY SWITCH
MASTER PROCESSOR INTERFACE
R.A.M. MEMORY
FLASH MEMORY
Vpp
MASTER PROCESSOR
EEPROM MEMORY
I2C3
I2C2
PLUNGER POSITION SENSOR
SENSOR POWER
MTR.ENC.INT
I2C1
MAS_FS
MAS_AUD
SYRINGE FLANGE DETECT
SYRINGE BARREL DETECT
SYRINGE SIZE SENSOR
SENSOR POWER
POWER-UP RESET
MOTOR DRIVE AND CONTROL
MOTOR
SLAVE PROCESSOR
FAILSAFE LATCH
AUDIO DRIVE/ CONTROL
SPEAKER
BUFFER/ FILTER
SERIAL DATA
BAT (Ub) SENSE
Vpp
CHARGE VOLTAGE REGULATOR
POWER SWITCH
Ub
5 VOLT REGULATOR
+5V SOURCE
EXTERNAL SERIAL DEVICE
EXTERNAL CHARGER
BATTERY PACK

Plunger Control (mechanical)

The syringe plunger is captured by a clamping device built into the plunger driver. Movement of the plunger is effectively controlled in the axial direction, thus limiting the potential for unintended drug flow due to siphoning. The plunger driver is designed so that the lead screw/halfnut drive is disengaged when the plunger clamping device is in the "open" position.

Drive Control (electronic)

Motor Drive

The motor is a conventional DC gearmotor driven by a four-transistor bridge. The drive control system uses pulse-width modulation. There are multiple safety systems included in the motor drive circuitry:

1) Motor current is electronically limited.

2) A detected "failsafe" error cuts off all four legs of the bridge, thus disabling the motor.

3) False drive data (e.g. processor "hang" or loss of motor pulses) will trip the "failsafe" subsystem.

PID Logic

The motor pulses are modulated by a Proportional Integral-Differential control algorithm.

Encoders

There are two drive encoders. The first is a rotary encoder built into the gear motor. There are 16 output pulses per revolution of the motor armature. The second encoder is a Hall-Effect pair that detects rotation of the lead screw assembly.

User Interface

Keyboard

The keyboard is a conventional vented-membrane type, using a tactile feedback silicone rubber overlay.

Data Display

Infusion information is displayed on a custom-designed LCD screen.

Status Lights

An array of front panel LEDs display pump status information.

Audio

There is a single audio transducer. The loudness can be set by changing the pump configuration. Program and status information is output as 4000 Hz tones of various duration. Failsafe errors alternate between 4000 Hz and 2000 Hz at a 1/2 Hz rate.

Serial Port

An external serial port is used to load the system's flash memory and EEPROM, and as a serial data port for various other special applications.

Control Subsystems

General

The output from each analog sensor is digitized by a single, multiplexed A/D converter and then processed in digital format.

Syringe Barrel Detect

The Barrel Detector is a series-connected, pressure-activated switch pair, built into the barrel clamp cradle. Both switches are closed only when the barrel is centered in the "V" shaped cradle.

Syringe Barrel Diameter Sensor

A linear-displacement potentiometer is built into the barrel clamp slider. The output voltage varies in direct proportion to the syringe barrel diameter.

Syringe Barrel Flange Detect

The syringe barrel flange is captured when the barrel clamp is closed. The Flange Detect switch, built into the barrel flange clamp, determines that the flange has been captured.

Plunger Position Sensor

The Plunger Position sensor is a linear-displacement potentiometer, mechanically coupled to the syringe plunger driver. The output varies in direct proportion to the plunger driver position.

Strain Gauge

The Strain Gauge measures the amount of force exerted on the lead screw drive mechanism, which is approximately the same as the force applied to the syringe plunger. This information is used to determine the presence of an occlusion.

Mercury Switch

The Mercury Switch senses whether the pump is in a vertical or horizontal orientation. This information is used as a force correction factor, to compensate for the weight of the drive screw assembly.

Power Supply

DC Regulation

There are two DC regulators. Battery charge power is current regulated to ensure proper charge rate. Circuit power is voltage regulated. An independant voltage sense circuit feeds back a reference voltage to the master processor.

Power Distribution

Most circuitry is powered by a regulated +5V supply. Failsafe alarm circuitry is powered directly from the battery. The digital and analog grounds are separated. Shield "ground" is isolated from system power.

Sensor Power

The analog sensors are powered from a strobed source, to reduce power consumption.

Battery

The battery is a conventional five-cell nickel-cadmium pack. The rated capacity is 1000 mAh. The charger and power regulator are optimized for this battery. There are no currently authorized substitutes.

Charger

The battery charger is a conventional direct plug-in, linear supply.

ESD Filter

The ESD filter shunts conducted and radiated external transients. The suppression devices are fast-acting and self-resetting.

Software: Application Level

Keystroke Recognition

During normal operations, there is an audible response to every keystroke. The design supports keydown auto-repeat. There is no keystroke rollover.

Safety

Multiple Keystrokes

Critical operations require at least two keystrokes in a specific sequence. The second keystroke must follow the first within a short time interval.

Safe Editing States

Program parameters can only be opened for editing under specific conditions. Some parameters (e.g. drug concentration) cannot be changed after the infusion has been initiated.

Configuration Check

During the power-up self test, the configuration information will be checked for validity. If not, a [RECONFIG] message appears, and the pump will not allow an infusion to be programmed.

Syringe Recognition

If Syringe Recognition is enabled, the actual syringe size will be compared to the programmed syringe size whenever the <START> button is pressed. In an emergency situation, it is possible to override Syringe Recognition. Multiple keystrokes and redundant prompting are part of the override procedure.

Software: Platform Level

Master-Slave Tasks

The Master processor is primarily dedicated to operating the pump. As a background task, the Master performs a continuous check of flash memory integrity and periodically checks specific RAM data areas.

The Slave processor checks the Master in four specific areas:

1) Timekeeping.

2) Verification that the Master is controlling the motor to the intended rate, within tolerance limits.

3) Classic "watchdog" check on system activity.

4) Checks the motor armature shaft encoder output against the lead screw's Hall Effect sensor.

Memory Partitioning

Three types of memory are used:

- Program data is stored in (volatile) RAM.

- The operating system (firmware) is stored in nonvolatile "Flash" memory.

- Configuration and calibration data is stored in EEPROM.

Roundoff

When a specific volume (such as a bolus) is delivered at a high flow rate, there may be a small "roundoff" difference between the programmed value and the total delivered value. This results from motor stepping.

Every delivery is a series of discrete motor steps. The size of these steps varies with the flow rate. The fastest rates use the largest steps. The delivery results from the summation of steps. It is unlikely that any specific volume will represent an exact number of steps. Thus, any delivered volume may be as much as one step different from the programmed value.

Limit warnings and alarms, such as Volume Limit, occur within one motor step of the designated limit.

Error Codes

Whenever a "failsafe" error occurs, the pump attempts to display an error code, in addition to the visible and audible alarms. There are two types of error code message: Master Failsafe and Slave Failsafe. Master Failsafe errors are displayed as [<line number> | <module name>]. Slave Failsafe errors are displayed as [<code number> | SLV ERR].

If possible, the error code message should be noted on the paperwork describing the pump failure. Diagnosis and repair of "failsafe" problems is a factory repair item only.

AS40A FIELD PERFORMANCE CHECK

1.0 PURPOSE

To provide the customer with a procedure to perform a quick evaluation of the general AS40A safety and performance.

This procedure must be performed in its entirety in order to verify overall operation.

This procedure may be used to comply with JCAHO recommendation for safety and performance testing.

This procedure is not intended to verify the pump's calibration after repairs. Repair calibrations are to be done by authorized trained service centers utilizing specific procedures and calibration gauges.

2.0 EQUIPMENT

Two 60 mL syringes (BD or Monoject) and one of each configured syringe, manufacturer and size that will be used with the AS40A. Samples must be unused and drawn from a current production lot.

Operation Manual: LAS40-01-700 or LAS40-01-705

One High Flow Rate Extension Set: 1M8521 or equivalent

Means of measuring .001'' and .072'' (ex: dial calipers)

Two pennies or 1/8'' spacer.

Optional: Calibrated PSI Gauge (minimum range 0 - 50 PSI),
1 mL Syringe (BD or Monoject).
Calibration Fixtures: CAS40-03-801 and CAS40-04-801
Timer > or = to 15 minutes.
Stopcock

3.0 PROCEDURE

To complete the procedure as written, the pump configuration must include:

"mL/hr" Mode: [Y] (enabled)
Syringe Recognition: [Y] (enabled)
PSI Range:[M] (medium)
Rate Range: [H] (high)
Volume Limit [N] (disabled)

3.1 VISUAL CHECK

3.1.1 Look for damage, sticky residue or any other condition that could influence performance. Clean as necessary. Ensure

that the barrel clamp is properly fitted to the case. Check the security of the pole clamp (if used).

3.1.2 Examine the charger plug and the charger port on the pump for signs of mechanical damage. Pins in the charger plug must be straight and intact.

3.1.3 Plug in the charger. The ON CHARGE light must turn on and stay on when the charger is plugged in and connected to the pump.

3.1.4 If the barrel clamp face (clear in color) is the type with a white pad, confirm the black button is present and firmly bonded in the pocket of the pad.

RECORD PASS OR FAIL upon completion of Visual Inspection.

3.2 SELF TEST

3.2.1 With the pump NOT connected to it's charger switch the pump ON. The pump will sound a beep. All segments of the LCD and the LEDs will turn on. Depress and hold the <STOP> key. The LEDs are set by a timer and will extinguish themselves. All segments of the LCD will remain visible as long as the <STOP> key is depressed. Verify all LEDs light and the LCD has all segments displayed. Refer to the Operation Manual for illustration of LCD with all segments on. Additional segments for an unused numeric digit and mL/min annunciator on some displays is acceptable. A second beep will sound after the <STOP> key is released. RECORD PASS OR FAIL

4.0 OPERATION

4.1 KEYPAD CHECK

4.1.1 After the pump completes the power-up sequence, momentarily press every key except the up arrow and the down arrow. Press in any order, one key at a time. Each keypress must result in an audible beep.

4.1.2 Press and hold any key except the up arrow and the down arrow. Then press any other key. There should be no response to the second key press. Do not hold down the <START> key for more than a few seconds, as this can result in a "stuck key" fail-safe alarm.

RECORD PASS OR FAIL upon completion of Keypad Check.

4.2 MECHANICAL CHECK

4.2.1 Check for slippage of the Syringe Driver by applying back pressure to the driver while a syringe is mounted on the

pump. A small amount of back and forth slack is normal, but if there is any sign of slippage, the pump requires repair. RECORD PASS OR FAIL.

4.2.2 Check the driver and the barrel clamp for free travel through their full range. Check the tab lock to be sure it opens when the barrel clamp is fully opened. RECORD PASS OR FAIL.

4.3 SYRINGE RECOGNITION

The Syringe Recognition subsystem measures the apparent diameter of the syringe barrel.

4.3.1 Select a syringe of the size and manufacturer normally used with this pump. If it is not possible to determine what syringes will be typically used, this check may be done using the calibration fixtures. CAS40-03-801 is recognized as a B-D 30. CAS40-04-801 is recognized as a B-D 5.

4.3.2 With the pump on, select "mL/hr" mode.

4.3.3 Fully retract the plunger driver, toward the top of the pump. Mount a syringe on the pump, then use either arrow key to select the syringe manufacturer. Press <CONFIRM> to lock in the selection.

4.3.4 The display will then change to [VERIFY xx mL] where "xx" represents the recognized syringe size. Do not press <CONFIRM>. The syringe size should be correctly recognized.

4.3.5 If the syringe size is correctly recognized, remove the syringe and press <CLR>. The syringe size will be cleared, and the syringe manufacturer field will flash. The text display will read [VERIFY (mfr)], where "mfr" represents the manufacturer name.

4.3.6 Select another syringe and repeat steps 4.3.3 through 4.3.5. Continue until all normally used syringes are checked. RECORD PASS OR FAIL.

4.4 TAB LOAD SWITCH

The Tab Load Switch is part of the flange clamp. When the barrel clamp is closed on a syringe, the tab load switch is held closed by the syringe barrel flange. If the switch opens while the plump is running, the pump issues a [CHECK SYRINGE] alarm.

4.4.1 With the pump on and "mL/hr" mode selected, mount any of the sample syringes in the barrel clamp.

4.4.2 Select and <CONFIRM> the syringe manufacturer and size.

4.4.3 Program the default value for the Rate field by pressing the up arrow key once, then <CONFIRM>.

4.4.5 Press <START>. Verify that the infusion delivery is in progress by observing that the RUN LEDs flash in a "falling drop" sequence.

4.4.6 Grasp the syringe barrel and push it toward the plunger driver (in an AXIAL direction). The axial movement forces the flange clamp open, simulating an improperly mounted syringe. A [CHECK SYRINGE] alarm should occur immediately. Press any key to silence alarm.

Note: Do not exert any side force (radial force) to the syringe barrel.

RECORD PASS OR FAIL

4.4.7 Remove syringe. Turn off pump.

4.5 CRADLE SWITCHES

The Cradle Switches determine whether the syringe is centered in the barrel clamp cradle. If either cradle switch is open when the infusion is started, a [CHECK SYRINGE] message occurs.

4.5.1 With the pump on and the "mL/hr" mode selected, fully retract the plunger driver toward the top of the pump.

4.5.2 Open the barrel clamp. Hold the tab load switch closed by inserting two pennies stacked together (or equivalent 1/8 in. spacer) in the tab load slot.

4.5.3 Select any sample syringe 20 mL or larger, and mount it upside down (luer tip pointing toward plunger driver) in the barrel clamp. The tip of the syringe should be located as close to the tab load slot as possible, without interfering with the pennies.

4.5.4 Select and <CONFIRM> the syringe manufacturer and size.

4.5.5 Program the default value for the RATE field by pressing the up arrow key once, then <CONFIRM>.

4.5.6 Press <START>. Verify that the infusion delivery is in progress by observing that the RUN LEDs flash in a "falling drop" sequence.

4.5.7 While the pump is running, carefully withdraw the syringe in an AXIAL direction.

4.5.8 Press <STOP>.

4.5.9 Press <START>. The audio alarm will beep once, the pump will remain in Standby state, and a [CHECK SYRINGE] message will be displayed. This verifies that the switch "open" condition has been detected. RECORD PASS OR FAIL

4.5.10 Carefully slide the syringe back in place (loosen barrel clamp if necessary), to close the cradle switches. Tighten the barrel clamp onto the syringe as necessary.

4.5.11 Press <START>. The infusion will resume, i.e. the RUN LEDs will flash in sequence and the text field will read [RUNNING] for a few seconds. This verifies that the switch "closed" condition has been detected.

Note: If the infusion does not resume, check the syringe centering and the barrel clamp pressure, then press <START>.

RECORD PASS OR FAIL

4.5.12 Press <STOP>. Remove syringe. Remove pennies/spacer.

4.6 DRIVER POSITION SENSOR

This position sensor detects the position of the plunger driver. Sensor function is verified by checking the operation of the [<10 MIN EMPTY] alert and [EMPTY] alarm.

4.6.1 Select an empty syringe and retract the plunger position slightly above the half-full mark. Mount the syringe on the pump, oriented so that the graduation marks are visible. Engage the plunger driver as for normal infusion delivery.

4.6.2 Program pump for correct manufacturer and syringe size if different than that used in previous test. Program an infusion rate that would deliver the full syringe volume in 20 minutes (ex. 180 mL/hr for a 60 mL syringe).

4.6.3 Start the infusion. A [<10 MIN EMPTY] alert should occur when the plunger is nominally at the half-full position. RECORD PASS OR FAIL.

4.6.4 Allow the infusion to continue until the pump stops. An [EMPTY] alarm should occur when the plunger approaches the "0 mL" mark on the syringe. The plunger should be within

0.072 in. (1.83mm) of the mark. Turn off pump. RECORD PASS OR FAIL.

4.6.5 Remove syringe.

4.7 ACCURACY TEST

4.7.1 Fill a 60 mL syringe with 60 mL of water and attach to extension set. Manually prime extension set.

4.7.2 Mount syringe on the pump. Turn on pump, program pump for correct manufacturer and size and select an infusion rate of 200 mL/hr.

4.7.3 Prime again using the pump's PURGE function. This will eliminate any slack in the system.

4.7.4 Ensure that the pump is connected to AC via the charger.

4.7.5 Record start volume from the syringe (for reference only). Use the graduations on the syringe to determine the volume.

4.7.6 Start the infusion. Record start time (for reference only).

Optional: Set timer for 15 minutes. Start timer.

4.7.7 Stop test after 15 minutes. Record the stop volume of the syringe. Subtract the stop volume from the start volume and record this volume as the delivered volume. The volume delivered must be between 47 mL and 53 mL. RECORD PASS OR FAIL.

Note: It is important to stop the test as close to 15 minutes as possible. An 18 second difference will result in a 1 mL error.

4.7.8 Remove syringe.

4.8 PRESSURE SENSOR

The axial force exerted on the plunger drive mechanism is measured by a strain gauge. This information is used to determine the presence of an occlusion, or other force that inhibits movement. Operation is checked by simulating an occlusion.

4.8.1 Fill a 60 mL syringe (BD or Monoject) with about 30 mL of water or saline solution. Provide a means of positively blocking fluid flow, i.e. a stopcock on the end of the syringe. Ensure that there are no air bubbles in the setup.

4.8.2 Mount the syringe on the pump, program for correct manufacturer and size and select an infusion rate of 100 mL/hr.

4.8.3 Press <PURGE> <START>. Repeat if necessary, until there is a steady flow of fluid from the syringe.

4.8.4 Press <START>. Verify that the infusion is running by noting fluid flow.

4.8.5 After about 30 seconds, close the stopcock or occlude the tubing. A [LINE OCCLUDED] alarm should occur within two minutes. Failure indicates a need to re-calibrate the pressure sensor. Press <STOP>.

Note: Results are dependent on materials and setup. Typically [LINE OCCLUDED] occurs within 1 minute.

RECORD PASS OR FAIL.

4.8.6 Remove syringe.

5.0 PRESSURE RANGE CHECK (OPTIONAL)

If a suitable pressure gauge is available, this procedure can be substituted for the "Pressure Sensor" check, above.

5.0.1 Prepare an unused 60 mL syringe (B-D or Monoject), filled to 30 mL with water. Connect the syringe to a pressure gauge, using a high flow extension set. Ensure that there are no air bubbles in the setup.

5.0.2 Mount the syringe on the pump and program for correct manufacturer and size and select and infusion rate of 100 mL/hr.

5.0.3 Position the pump horizontally with the ``ON/OFF'' switch down and the barrel clamp up. To avoid any problems with headheight the PSI meter should be positioned on the same bench top as the pump.

5.0.4 Start the infusion and note the pressure at which the LINE OCCLUDED] alarm occurs. Press <STOP>. The occlusion pressure reading should be between 9 and 15 PSI. RECORD PASS OR FAIL.

5.0.5 Repeat steps 5.0.1 through 5.0.4 using a completely filled 1 mL syringe and a delivery rate of 10 mL/hr. The occlusion pressure reading should be between 14 and 41 PSI. RECORD PASS OR FAIL.

5.0.6 Turn off pump.